

# **GUIDE FOR THE PREPARATION OF APPLICATIONS FOR MEDICAL PROGRAMS**

## **NOTICE**

Enclosed with the "Guide for the Preparation of Applications for Medical Programs, RH 2010, is a listing of those sections of the associated appendices affected by the adoption of Title 10, Code of Federal Regulations, Part 20. Please review the listings and the appropriate regulations when committing to the various appendices or when developing equivalent procedures so that your program will be adequate and in compliance. The listing includes additions and some correction in an attempt to make the guide current with new technologies.

# **GUIDE FOR THE PREPARATION OF APPLICATIONS FOR MEDICAL PROGRAMS**

To Assist Those Applying for a License or License Amendment  
for Medical Use of Radioactive Materials

State of California  
Department of Health Services  
Radiologic Health Branch, MS 7610  
P.O. Box 997414  
Sacramento, CA 95899-7414

## **Listing of Affected Appendices to the “Guide for the Preparation of Applications for Medical Programs”**

NOTE: A change in regulations or additional regulations affecting appendices are asterisked.\*

### Appendix A – Program for Maintaining Radiation Exposure at Medical Institutions ALARA (Item 7 of application)

- |          |  |
|----------|--|
| Page A-1 | Delete: Section 30253<br><b>ADD: 10 CFR Part 20, Section 20.1101 (b)*</b>  |
| Page A-2 | (Item 2) The Radiation Safety Committee is not applicable for applications for use by individuals.   |
| Page A-3 | (Table 1) Investigational Levels were developed prior to the adoption of 10 CFR Part 20. You may choose to use these values or to develop other values. Submission of other values will need justification |
| Part A-5 | <b>ADD: 10 CFR Part 20, Section 20.1101*</b><br><b>ADD: 10 CFR Part 20, Section 20.2101 – 20.2110*</b>   |

### Appendix B – Medical Radiation Safety Committee (Items 5 and 8 of application)

- |          |   |
|----------|---|
| Page B-1 | Delete: Section 30280<br><b>ADD: Title 17, CCR, Section 30255*</b>  |
| Page B-2 | <b>ADD: Title 17, CCR, Section 30195 (a) and (b)</b><br><b>ADD: Title 17, CCR, Sections 30321 and 30321.1</b> |

### Appendix C – Acceptable Training and Experience for Medical Uses of Radioactive Material (Items 4 and 9 of application)

- |          |   |
|----------|---|
| Page C-1 | Delete: (Item 1) To qualify as adequately trained to use or directly supervise the use of radioactive material listed in Group 1 of the well-established Medical Uses List (RH 2010R), a physician should have:             |
| Page C-2 | Delete (Item 2) To qualify as adequately trained in use or directly supervise the use of radioactive material listed in Group 1, 2, and/or 3 of the well-established Medical Uses List (RH 2010R), a physician should have: |

Appendix C – Acceptable Training and Experience for Medical Uses of Radioactive Material  
(Continued)

Page C-4	(Alternatives)	When certification is provided by the Society of Nuclear Cardiology, Nuclear Cardiology will be recognized.
	Delete: (Item 3)	...,RH 2010R,...
Page C-5	Delete: (Item 5)	...,RH 2010R,...
Page C-6	<b>ADD:</b> (Item c)	<b>If application involves the use of an HDR, LDR, or Pulsed Remote Afterloaders, clinical training in the appropriate modality must be obtained in addition to other clinical experience.</b>

Appendix D – Instrumentation  
(Item 10 of application)

Page D-1	<b>ADD:</b> (Item 1.a)	<b><u>Type of detector (pancake, end window, side window, energy compensated G.M., thin crystal, thick crystal)</u></b>
	<b>ADD:</b> (Item 4)	<b>room monitors, waste monitors</b>
	<b>ADD:</b>	<b>10 CFR Part 20, Section 20.1501 (b)* 10 CFR Part 20, Section 20.1501 (c)*</b>

Appendix E – Calibration of Instruments  
(Item 11 of application)

	<b>ADD:</b>	<b>10 CFR Part 20, Section 20.1501 (b)*</b>
Page E-5	<b>ADD:</b> (Section 3)	<b>Beta emitting radiopharmaceuticals may be difficult to accurately measure in the standard dose calibrators. To calibrate the dose calibrator, the procedures recommended by the radiopharmaceutical manufacturer will be followed.</b>

Appendix F – Procedures for Ordering and Receiving Radioactive Material  
(Item 14 of application)

**ADD: 10 CFR Part 20, Section 20.1906\***

Appendix G – Procedures for Safely Opening Packages  
(Item 15 of application)

**ADD: 10 CFR Part 20, Section 20.1906**

**Recommendation:** (Item 8) **Replace 7 mg/cm<sup>2</sup> with 2 mg/cm<sup>2</sup>**

**DELETE:** See Exhibit 3 for a sample record form.

**ADD:** Item 9. **All labeled packages must be monitored for contamination.**

Appendix H – Records of Radioactive Materials Use  
(Item 16 of application)

**ADD: Title 17, CCR, Sections 30321 and 30322**

Appendix I – General Rules for the Safe Use of Radioactive Material  
(Item 17 of application)

**ADD: 10 CFR Part 20, Section 20.1101\***

**ADD: 10 CFR Part 20, Section 20.1501\***

Appendix J – Area Survey Procedures  
(Item 18 of application)

**ADD: 10 CFR Part 20, Subpart F, Sections 20.1501 – 20.1502\***

**Correction:** (Item 1) ...(see item 10 of application)...

Appendix K – Emergency Procedures  
(Item 19 of application)

**ADD: 10 CFR Part 20, Section 20.1101\***

**ADD: Title 17, CCR, Section 30255**

Appendix L – Waste Disposal  
(Item 20 of application)

**Delete:** (Item 1) Section 30287 (see Exhibit 10)

**ADD:** (Item 1) **10 CFR Part 20, Subpart K, Sections 20.2001 – 20.2007\***

Appendix M – Therapeutic Use of Radiopharmaceuticals  
(Item 21 of application)

Delete: (Item 3) Section 30278  
**ADD:** (Item 3) **10 CFR Part 20, Section 20.1902\***

Delete: (Item 6) Section 30268  
**ADD:** (Item 6) **10 CFR Part 20, Section 20.1301\***

Appendix N – Therapeutic Use of Sealed Sources  
(Item 22 of application)

Delete: (Item 2) Section 30278  
**ADD:** (Item 2) **10 CFR Part 20, Section 20.1902\***

**ADD:** (Item 4) **Surveys of patient's room, adjacent rooms, rooms above and below and surrounding areas will be conducted...**

Delete: (Item 7) Section 30268  
**ADD:** (Item 2) **10 CFR Part 20, Section 20.1301\***

**ADD:** (Item 8) **...care to patient as per 10 CFR Part 20, Section 20.1502\***

**ADD:** (Item 9) **At the conclusion of treatment, a survey shall be performed Title 17, CCR, Section 30321.1, to ensure that all...\***

Delete: (Item 11 b) Nurses should  
**ADD:** (Item 11 b) **Nurses shall spend only the minimum time necessary near a patient for routine nursing care as per 10 CFR Part 20, Section 1101 (b)\***

Delete: (Item 11 c) ...dosimetry device should  
**ADD:** (Item 11 c) **...dosimetry shall be obtained immediately as per 10 CFR Part 20, Section 20.1502...\***

**ADD:** (Item 11 d) **Regulations found in 10 CFR Part 20, Section 20.1208 shall be followed.\***

**ADD:** Item 11 o) **Emergency procedures will be available at the nursing station and will contain instructions for the following:**

**ADD:** Item 11 q) **The source custodian shall verify that all sources have been accounted for and placed in designated storage as per Title 17, CCR, Sections 30321 and 30321.1.**

Appendix O – Procedures and Precautions for Use of Radioactive Gases  
(Item 23 of application)

Page O-2      Delete:    (Item 5 d&e) ...Section 30266  
                  **ADD:**        (Item 5 d&e) **10 CFR Part 20, Section 20.1201\***

                  Change:    (Item 5 d&e)  $10^{-5}$  in equations to  $10^{-4}$  uci/ml

Appendix P – Guidance on Requests for License Amendments and License Terminations

**ADD:**        (Item c)      **7. Patient instructions.**  
   **8. Emergency procedures and instructions.**

Delete:       (Item e (2)(c)) ...Section 30269  
**ADD:**        (Item e (2)(c)) ...**10 CFR Part 20, Sections 20.1301, 20.1302, and**  
   **Appendix B\***

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## **1. INTRODUCTION**

### **1.1 Purpose of Guide**

This guide describes the type and extent of information needed by the State of California, Department of Health Services, Radiologic Health Branch, to evaluate an application for a specific license for the possession of radioactive material and its use in or on human beings. This type of license is provided for under Section 30195 (a) and (b) of the California Radiation Control Regulations.

Usually a single radioactive material license is issued to cover an institution's entire radioisotope program. Separate licenses are not normally issued to different departments of a medical institution, nor are they issued to individuals associated with the institution.

The applicant should carefully review the regulations and this guide and should submit all information requested. Additional information may be requested when necessary to provide reasonable assurance that the applicant has established an adequate radiation safety program. Such requests may delay final action on the application.

### **1.2 Applicable Regulations**

In addition to Section 30195 (a) and (b), the following sections of the California Radiation Control Regulations pertain to this type of license:

<b>Section No.</b>	<b>Requirement</b>
30253	Requires each licensee to develop an ALARA program.
30265	States maximum permissible doses to whole body, extremities, skin for radiation workers.
30265.1	Requires determination of prior dose to individuals working in areas where internal dose assessment or personnel monitoring is required.
30266	States maximum permissible concentration of radioactive materials in controlled areas.
30268	States maximum permissible radiation levels in areas accessible to nonradiation workers.
30275	Requires periodic radiation surveys and leak tests of sealed sources.
30276	Requires personnel monitoring if 25 percent of the maximum permissible dose may be exceeded.
30277	Requires provision for internal uptake assessment where indicated by or appropriate to the nature of potential exposure.

<b>Section No.</b>	<b>Requirement</b>
30278	Requires posting of radiation areas and labeling of radioactive material.
30280	Requires instruction of personnel. Requires availability of copy of regulations. Requires posting of "Notice to Employees" (form RH 2364). Requires provision of exposure record to employee.
30285	Prohibits disposal of radioactive waste except as specifically authorized.
30293	Requires maintenance of records of surveys, tests, receipt, disposal of sources, and exposure records of personnel.
30295	Requires notification of the Department of certain incidents involving radiation sources.
30297	Requires reports of overexposures and excessive levels and concentrations of radioactive materials.
30298	Stipulates conditions for vacating installations.
30321	Requires custodianship of sealed sources. Requires protective enclosure for stored sealed sources. Section 30321.1 requires confirmation of removal of implants.
30322	Stipulates actions to be taken following misadministration as defined in Section 30100.
30373	Requires that the rules and regulations of the U.S. Department of Transportation be followed when radioactive materials are transported within California.

The above list is not complete but includes those sections of widest applicability and those which have most often led to citation of the licensee for noncompliance with regulations at the time of inspection.

### **1.3 Items Requiring Additional Application Forms**

A separate form RH 2000D must be submitted for kilocurie sources used in teletherapy facilities. A specific licensing guide, form RH 2011, for teletherapy applications is available on request from the Department.

Applicants wishing authorization for human use of radioactive material or pharmaceuticals which are not on the Department's "Well-Established Medical Uses" list or which are not approved under a New Drug Application (NDA) by the U.S. Food and Drug Administration (USFDA) or the California Food and Drug Branch must request special authorization using form RH 2000E or RH 2000J as appropriate.

Form RH 2000E must be submitted if the physician is independently participating in Phase 3 clinical studies under a “Notice of Claimed Investigational Exemption for a New Drug” (IND) accepted by the USFDA or the California Food and Drug Branch.

For Phase 3 studies sponsored by a manufacturer under an accepted IND, the participating physician must submit form RH 2000J.

Physicians participating in Phase 3 IND studies must submit a copy of the “Statement of Investigator” (USFDA form 1573) to the Department for each investigation prior to its initiation. If the investigator is not the physician named on the license as responsible for Phase 3 IND studies, the named physician must either countersign or attach a cover letter to the copy submitted indicating approval and acceptance of responsibility for the study.

The “Well-Established Medical Uses” list (form RH 2010R) has been prepared by the Department’s Medical Advisory Committee and includes those medical procedures and associated maximum radiopharmaceutical dosages considered to be good medical practice. Applicants wishing to use these materials for other indications or to routinely use larger dosages than those indicated must request special authorization using form RH 2000N. Occasionally, a larger dosage may be administered to a specific patient if in the physician’s best medical judgment the larger dosage is warranted. Submission of RH 2000N is not required under these circumstances, but records of the justification for the larger dose must be maintained.

The Department’s “Well-Established Medical Uses” is updated periodically, and copies are available from the Department.

#### **1.4 As Low As Reasonably Achievable (ALARA) Philosophy**

Section 30253 of the California Radiation Control Regulations requires each licensee to make every reasonable effort to maintain radiation exposures and releases of radioactive materials in effluents to unrestricted areas as low as is reasonably achievable taking into account the state of technology and the economics of improvements in relation to benefits to the public health and safety.

Each medical licensee (except for only Group 7 licensees—see item 6) must have a formal ALARA program. The success of such programs depends on the cooperation of each person who works at the licensee’s facility. A model ALARA management program is contained in Appendix A of this guide.

Specific radiation safety, operating, and emergency procedures for radiation work are important elements in any dose reduction program. Recent data throughout the medical community indicates that occupational exposures less than ten percent of the annual maximum permissible dose are readily achievable with proper attention to good practice.

Model radiation protection procedures are provided as appendices to this guide. Other useful information can also be found in the referenced technical reports.

## 1.5 Types of Materials Licenses

### 1.5.1 General License

Section 30192.5 of the California Radiation Control Regulations establishes a general license authorizing physicians, clinical laboratories, veterinarians, and hospitals to possess certain minute quantities of radioactive material for in vitro clinical or laboratory tests not involving the internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals. It is not necessary for the general licensee to register with the State and receive a registration number prior to receiving or using the material for in vitro testing. If larger quantities or other materials are needed, an application must be submitted to the Department for a specific license.

### 1.5.2 Specific License

In California, all human uses of radioactive materials require a specific license. (Information summarizing “human use” is provided in item 8 of this guide.) There is no general license authorizing human use.

Licenses issued to physicians (or groups of physicians) for private practice specify the radioactive materials and the clinical uses that may be performed by the physician(s) to whom the licenses are issued. Such licenses are issued pursuant to Section 30195 (b), to physicians who are located in private offices and not on hospital premises. It is not required that a Radiation Safety Committee be formed. The private practice license *does not permit other physicians to obtain clinical radioisotope training and experience under it.*

Specific licenses of limited scope issued to medical institutions specify the radioactive materials and the clinical uses that may be performed by the physician(s) named on the institution’s license. The regulations in Section 30195 (a) require an institutional licensee to have a Radiation Safety Committee (see Appendix B to this guide) to evaluate all proposals for clinical research, diagnostics, and therapeutic uses of radioactive materials within the institution. The physicians named on the institution’s license conduct their programs with the approval of the Radiation Safety Committee. Training and experience criteria for physicians are outlined in Appendix C to this guide.

Specific licenses of broad scope for medical use, i.e., licenses authorizing multicurie quantities and types of radioactive materials for unspecified uses, are issued to institutions that: (1) have had previous experience operating under a specific institutional license of limited scope and (2) are engaged in medical research as well as routine diagnosis and therapy using radioactive materials. Such programs operate under the supervision of a Radiation Safety Committee. Individual users are not named on the license nor are radioactive materials limited to specified uses. Individual users and procedures are approved by the institution’s medical Radiation Safety Committee. Physicians may obtain basic and clinical training and experience in the use of radiopharmaceuticals in such programs. This type of license is not appropriate for most institutions using radioactive materials in medical programs. Limited scope licensees wishing to apply for broad scope authorization should contact the Department for further information and application forms.

## **1.6 Administration of Radioactive Materials or Radiation Sources by Unauthorized Individuals**

A certified or special permit nuclear medicine technologist or radiation oncology technician employed in a nuclear medical program is not ordinarily designated as an authorized user on the radioactive material license. The technologist's use of radioactive materials is at the direction and under the supervision of a responsible physician designated as a user. Responsibility remains with the responsible physician. California regulations do not permit authorization for human use to be granted to anyone other than a physician.

A physician who is not named on the license cannot perform the functions described for the technologist unless the physician has met the requirements for certification as a nuclear medicine technologist and performs the above function at the direction of an authorized user.

Residents in training in teaching hospitals may use radioactive materials only under the direct supervision of a preceptor-physician named as an authorized user on the hospital license. The authority of a preceptor to so supervise the human use of radioactive materials must be specifically granted by a condition in the hospital's license. This authority is ordinarily granted by a condition stating that radioactive materials may be used by or under the supervision of the named preceptor-physician. Responsibility remains, of course, with the preceptor-physician.

## **1.7 Mobile Nuclear Medicine Providers**

Mobile nuclear medicine service licensees operating at nonlicensed physician offices, clinics, and hospitals must obtain a letter signed by the management of each client authorizing the use of radioactive material at the client's facility. The licensee shall retain the letter for three years after the last provision of service.

If the mobile service provides services at a licensed client's facility, all use of radioactive material shall be conducted in accordance with the client's license. A condition on the client's license would indicate authorization to use a mobile service. In the absence of this condition, a mobile service may provide nuclear medicine services at licensed facilities only in case of emergencies. This service must be documented.

Mobile nuclear medicine service licensees are not permitted (except by license authorization) to have radioactive materials delivered directly to the client's facility by the manufacturer or distributor.

## **1.8 Records and Reports of Misadministration**

Misadministration of radiopharmaceutical or radiation is defined as administration of:

- a. A radiopharmaceutical or radiation from a sealed source other than the one intended;
- b. A radiopharmaceutical or radiation to the wrong patient;



- c. A radiopharmaceutical or radiation by a route of administration other than that intended by the prescribing physician;
- d. A diagnostic dosage of a radiopharmaceutical differing from the prescribed dosage by more than 50 percent;
- e. A therapeutic dosage of a radiopharmaceutical differing from the prescribed dosage by more than 10 percent; or
- f. A therapeutic radiation dose from a sealed source such that errors in the source calibration, time of exposure, and treatment geometry result in a calculated total treatment dose differing from the final prescribed total treatment dose by more than 10 percent.

Following a therapeutic misadministration, the licensee shall notify the Department, the referring physician, and the patient or guardian (unless the referring physician agrees to inform the patient or based on a medical judgment, the referring physician believes that telling the patient or guardian would be harmful).

The initial notification shall be made within 24 hours and shall be followed within 15 days with a written report as stipulated in Section 30322.

Following a diagnostic misadministration, the licensee shall promptly investigate the cause and maintain a record of such investigation for Department to review. Within 15 days, the licensee shall notify (in writing) the Department and the referring physician, as stipulated in Section 30322.

## **1.9 Visiting Authorizing User, Locum Tenens**

In order to allow for coverage during vacations, illness, etc., and to expedite the process of adding new physicians to the staff, the following condition will be added to all institutional medical licenses:

For a period not to exceed 60 days in any calendar year, a visiting physician is authorized to use licensed material for human use under the terms of this license, provided the visiting physician has the prior written permission of the hospital's administrator and its medical Radiation Safety Committee, is registered with the California Board of Medical Certification, and meets one of the following criteria:

- (1) Is specifically named as a user on a California license authorizing human use, and performs only those procedures for which they are specifically authorized by a California license, and for which the host licensee is authorized. OR

- (2) Is specifically named as a user on a Nuclear Regulatory Commission (NRC) or Agreement State license authorizing human use, and performs only those procedures for which they are specifically authorized by the NRC or Agreement State license, and for which the host licensee is authorized.

The licensee shall maintain for inspection copies of the written permission and certification specified above, and of the licenses specified in (1) or (2) above. These records shall be maintained for three years from the time the licensee grants permission under this condition.

### **1.10 Minor Radiation Safety Program Changes**

A licensee may make the following minor changes in the radiation safety program without an amendment from the Department provided that written records of such changes are maintained for inspection by the Department or until the license is renewed or terminated.

- a. Changes in the membership of the Radiation Safety Committee except for the committee chairman and Radiation Safety Officer and provided the changes do not alter the representative characteristics of the committee.
- b. Replacement of equipment if there is no change in the instrument type and function.
- c. Reassignment of service contracts for (1) personnel dosimetry if the licensee commits to use a National Voluntary Laboratory Accreditation Program (NVLAP) accredited service organization and (2) for instrument calibration, waste disposal, safety surveys, and leak tests, if the licensee commits to use service groups authorized by the Department or NRC/Agreement State to provide such services.

A copy of the service group's accreditation or license must be maintained for inspection by the Department.

## **2. LICENSE FEES**

An annual fee is required for most types of licenses and is subject to an annual cost-of-living adjustment pursuant to Section 113 of the California Health and Safety Code. The applicant should refer to Sections 30230, 30231, and 30232 of the California Radiation Control Regulations.

## **3. FILING AN APPLICATION**

A license application for specific authorization for human use should be submitted on form RH 2000, "Application for Materials License—Medical". The applicant must complete all items on the application form in sufficient detail for the Department to

determine that the applicant's equipment, facilities, training, and experience, and radiation protection program are adequate to protect health and minimize danger to life and property.

Since the space provided on form RH 2000 is limited, the applicant may append separate sheets for item 7-25 listed on the form or may indicate by checking the appropriate box that specific procedures will be followed. Each separate sheet should contain the item number and the application date in the lower right corner.

One copy of the application, with all attachments, shall be retained by the applicant since the license will require, as a condition, that the licensee follow the statements and representations set forth in the application and any supplement to it. The *original* and *one copy* shall be mailed to:

State of California  
Department of Health Services  
Radiologic Health Branch  
P.O. Box 997414  
Sacramento, CA 95899-7414

#### **4. CONTENTS OF AN APPLICATION**

This section of the guide explains the information requested in the application. The appendices provide either additional information on specific subject area or model procedures which the applicant may adopt in response to items on the application form. Exhibits, in the form of sample application forms and work sheets, are provided to assist applicants in completing the application.

**Item 1.a.** Enter the name, mailing address, and telephone number of the applicant. If the request is for an individual or group practice license, enter the name of the physician or partnership.

**Item 1.b.** List the addresses and locations where radioactive material will be used or stored if other than the address stated in item 1.a. If multiple addresses are to be used, explain the extent of use at each facility and the equipment available at each facility for the safe use of radioactive materials.

**Item 2.** Enter the name and telephone number (including area code) of the individual to be contacted regarding the application.

**Item 3.** Indicate whether this is an application for a new license, an amendment to a existing license, or a renewal of a existing license.

**Item 4.** List the full names of all physicians who will use or directly supervise the use of radioactive materials. These are the physicians who use the radioactive materials directly or who are direct supervisors of physicians, technicians, technologists, or other paramedical personnel to whom specific activities are delegated.

When a preceptorship program at an institution is specifically authorized by license condition as outlined in 1.5 above, physicians under direct supervision of the named users may be delegated the following responsibilities:

- a. Approval of procedures involving the administration to patients of radiopharmaceuticals or the application to patients of radiation from radioisotope sources.
- b. Prescription of the radiopharmaceutical or source of radiation and the dosage to be administered.
- c. Determination of the route of administration.
- d. Administration of dosage to patients, within limits and conditions permitted by applicable state laws.
- e. Interpretation of the results of diagnostic procedures in which radiopharmaceuticals are administered.

Certified or special permit nuclear medicine technologists and radiation oncology technicians, under a supervisor's supervision, may be delegated the following activities under certain conditions (see Item 9):

- a. Preparation and quality control testing of radiopharmaceuticals and sources of radiation.
- b. Measurement of radiopharmaceutical dosages prior to administration.
- c. Use of appropriate instrumentation for the collection of data to be used by the physician.
- d. Administration of radiopharmaceuticals and radiation from radioisotope sources to patients within limits and conditions permitted under applicable state laws.
- e. Custodianship of sealed or solid sources of radioactive materials.
- f. Collection of wipe test samples of contamination and/or leakage test of sealed or solid sources of radioactive materials. Analysis of such wipe test samples if procedure is approved in the license.

**Item 5.** State the name and title of the person designated by and responsible to the institution's management for the coordination of the institution's radiation safety program.

**Item 6.** Human use of radiopharmaceuticals and other radioactive sources are grouped into 12 categories of uses. The specific radioactive materials, forms, dosages, and study/treatment are provided in RH 2010 ("Well-Established Medical Uses") and are briefly summarized below.

The applicant may check the group numbers for which the licensee is requested. Where more detailed information is required (as in Groups 6 and 7), the applicant should provide the information as requested.

**Group 1 – Use of Radioactive Materials in Diagnostic Studies Involving Measurement and Uptake, Dilution, or Excretion But Not Involving Imaging**

This includes any radioactive material in a radiopharmaceutical for diagnostic use for which an NDA has been approved by the USFDA or by the California Department of Health Services, Food and Drug Branch.

**Group 2 – Use of Radioactive Materials in Diagnostic Studies Involving Imaging and Localization**

- a. Any radioactive material in a radiopharmaceutical for diagnostic use for which an NDA has been approved by the USFDA or by the California Department of Health Services, Food and Drug Branch.

If Xenon-127 and/or Xenon-133 has will be used, the applicant must submit information on facility ventilation and precautionary measures.

- b. Any radioactive material in a radiopharmaceutical prepared from a generate eluate and a reagent kit noted in Group 3 below and for a use specified therein.

**Group 3 — Use of Radioactive Materials and/or Generators, and Reagent Kits for Preparation of Radiopharmaceuticals**

- a. Any generator for which and NDA has been approved by the USFDA or by the California Department of Health Services, Food and Drug Branch, as a source of eluate for user-prepared radiopharmaceuticals.
- b. Any reagent kit for which an NDA has been approved by the USFDA or by the California Department of Health Services, Food and Drug Branch, for user preparation of a radiopharmaceutical.

**Group 4 – Use of Radioactive Material in a Pharmaceutical for Internal Therapy That Usually Does Not Require Hospitalization**

**Group 5 – Use of Radioactive Material in a Pharmaceutical for Internal Therapy That Usually Requires Hospitalization For Purposes of Radiation Safety.** This group is not usually granted to private practice applicants.

**Group 6 – Use of Sealed or Solid Sources of Radioactive Materials for Brachytherapy or Ophthalmic Treatment.** Brachytherapy authorization is not usually granted to private practice applicants except for storage.

These sources must be manufactured, labeled, packaged, distributed pursuant to 10 Code of Federal Regulations (CFR) 32.74 or equivalent Agreement State regulations (except for sources manufactured prior to August 16, 1974).

The nuclide, physical form, activity of each source, total number of sources, and manufacturer's name must be provided (palladium, iodine, iridium, and gold seeds are excepted).

**Group 7 – Use of Sealed or Solid Sources of Radioactive Material in Devices For Certain Diagnostic Studies Involving Transmission or Excitation**

The nuclide, activity, device manufacturer, and model number must be provided.

**Group 8 – Use of Sealed or Solid Sources of Radioactive Material for Teletherapy of Cancer**

Form RH 2000D must be attached. (See section below for Teletherapy and Service Authorization.)

**Group 9 – Use of Sealed or Solid Sources of Radioactive Material as Marker And Calibration Sources, Depleted Uranium For Accelerator Shielding, Survey Meter Calibration Sources, or Use of Radioactive Material For In Vitro or Animal Studies**

For sealed sources of radioactive material, except special nuclear material, in amounts not to exceed 15 millicuries per source, contained in calibration or reference sources that have been manufactured, labeled, packaged, and distributed in accordance with a specific license issued to the manufacturer pursuant to 10 CFR 32.74 or equivalent Agreement State regulations, only the total number of sources and total possession limit should be specified. List the manufacturer's name, model number, and activity (in millicuries) for all other sealed sources.

For radioactive materials to be used for animal or in vitro studies, indicate the nuclide, form, possession limit, and intended use and any limitations. The applicant should contact the Department for additional requirements.

**Group 10 – Physician-Sponsored Nonroutine Medical Uses of Radioactive Materials.** Form RH 2000E and USFDA form 1573 must be submitted.

Any radioactive material in a radiopharmaceutical for diagnostic or therapeutic use for which an IND has been accepted by the USFDA or by the California Department of Health Services, Food and Drug Branch. Only Phase 3 clinical investigations are authorized under this section.

**Group 11 – Manufacturer-Sponsored Nonroutine Medical Uses of Radioactive Materials.** Form RH 2000J and USFDA form 1573 must be submitted.

Any radioactive material in a radiopharmaceutical for diagnostic or therapeutic use for which an IND has been accepted by the USFDA or by the California Department of Health Services, Food and Drug Branch. Only Phase 3 clinical investigations are authorized under this section.

**Group 12 – Use of Sealed or Solid Sources of Radioactive Materials in Pacemaker Devices.** The nuclide, activity, device manufacturer, and model number must be provided.

**All Groups** – The possession limit for each group requested must be specified. Note that the possession limit includes materials stored for future use and those held as radioactive waste.

### **Teletherapy and Service Authorization**

Form RH 2000D must be submitted for teletherapy authorizations. Guidance for completing this form is provided in the Teletherapy Licensing Guide, RH 2011. Authorization for teletherapy of cancer is normally granted in three stages.

The first stage allows for installation, possession, and operation for physical measurements only. Following the receipt of notification by the licensee that the survey of the unit meets the requirements of the regulations, a second authorization is granted for temporary (normally 30 days) therapeutic use of the unit pending review of the licensee's survey report. The final authorization is granted after the receipt and review of the licensee's post-installation survey report.

Installation, removal of a teletherapy unit, or any service which requires removal or insertion of a source or source assembly, or any service which affects the source integrity and position either physically, electrically, or electronically requires a specific license authorization. This authorization normally granted only to the manufacturer or its service representative. However, single-job authorizations may be issued to other licensees if the applicant.

- a. Provides evidence of training and experience in performing the procedure that is requested. The training and experience must be on the same make and model as the teletherapy unit involved; a similar model of the same manufacturer would also qualify.
- b. Possess the equipment and tools designed by the manufacturer for the work proposed, or demonstrates that available equipment and tools are equivalent and capable of accomplishing the procedure with equal assurance of safety.
- c. Possesses the installation or service manuals prepared by the manufacturer for the work proposed, or demonstrates that available manuals are equivalent in specificity and clarity.

**Item 7.** Each medical licensee (except those applying for Group 7 procedures only) must have a formal ALARA program. Management should make a formal policy commitment to the ALARA philosophy and implement the commitment with adequate resources.

Appendix A of this guide contains ALARA management program and may be adopted by licensee in lieu of submitting equivalent procedures.

**Item 8.** In accordance with Section 30195 (a), a institution applying for a radioactive material license for human use is required to establish a Radiation Safety Committee of at least four members (not required for clinics). This committee evaluates all proposals for, and maintains surveillance over, the research, diagnostic, and therapeutic uses of

radioactive materials. It is recommended that this committee also be responsible for assuring that all uses of radiation machines are carried out in accordance with the California Radiation Control Regulations. It is the committee's obligation to reduce both personnel and patient exposure to the minimum while pursuing the medical objective. Membership of the committee should consist of at least:

- a. A physician specializing in nuclear medicine, internal medicine, hematology, therapeutic radiology, diagnostic radiology, or pathology who will use or directly supervise the use of radioactive materials in humans.
- b. A person with special competence in radiation safety/Radiation Safety Officer.
- c. A representative of the institution's management.
- d. A representative of the nursing service.

Other members may be included in the committee as the licensee see appropriate. The Radiation Safety Officer and the committee chairperson should preferably not be the same individual. Any changes in the Radiation Safety Officer or committee chairperson will require an amendment to the license. The applicant must maintain a current copy of the committee membership for inspection by the Department.

Submit the following information:

- a. The statements of authority, responsibility, and duties of the committee (Radiation Safety Officer for clinics).

Each licensee shall provide the Radiation Safety Officer (and at medical institution, the Radiation Safety Committee) sufficient authority, organizational freedom, and management prerogative to:

- (1) Identify radiation safety problems.
- (2) Initiate, recommend, and provide corrective actions.
- (3) Verify implementation of corrective actions.

The licensee shall establish and state in writing the authorities, duties, and responsibilities of the Radiation Safety Officer and the Radiation Safety Committee where applicable. A copy of these statements shall be forwarded to the Department.

- b. The name and specialty of the Radiation Safety Committee Chairperson.
- c. The specialty of each membership of the committee.

Appendix B of this guide contains an example of typical responsibilities and duties for a Radiation Safety Committee. Indicate, by checking the appropriate box in Item 8, that the responsibilities, duties, and meeting frequency will be as described in Appendix B or propose alternatives. If the responsibilities, duties, or meeting frequency will be different from those described, submit a complete description and justifications. If the



Chairperson of the Committee and the Radiation Safety Officer are not individuals named in Item 4, submit complete descriptions of the training and experience.

### **Item 9. Individuals Responsible for Radiation Safety Programs and Their Training and Experience**

The responsible individuals are the authorized users and the Radiation Safety Officer. The regulations require that the applicant be qualified by training and experience to use the requested radioactive material in such a way as to ensure public health and minimize danger to life or property.

Authorized users in medical licenses perform the following specific functions:

- a. Examination of patients and review of medical records to determine if a radiation procedure is appropriate.
- b. Radiopharmaceutical and/or radiation dose prescription and route of administration.
- c. Dose administration, or direction of the technologists (teletherapy technician if appropriate) in such function.
- d. Interpretation of the results of the diagnostic or therapeutic procedures.

For routine procedures, items b and c above may be delegated to a qualified technologist/technician if the licensee submits to the Department a list of those procedures and under what conditions the procedures may be executed by the technologist. Nothing in this section absolves the authorized user of responsibility of the activities and omissions of the supervised individual.

In teaching hospitals and where a condition in the license provides for a preceptor-physician supervisory arrangement, items a through d above may be delegated to a supervised physician. Responsibility for all activities or omission of the supervised physician still lies with the authorized preceptor-physician.

#### **a. Authorized User(s) for Medical Use**

If the physician has been previously authorized to use the radioactive material requested in this application, it is necessary to submit only the previous license number (if issued by the State of California and the user has been named on the license within the past five years) or a copy of the license (if issued by the NRC or another Agreement State).

If the physician has not been previously authorized to use the radioactive material being requested, or a copy of the previous license is not available, submit a complete description of user's training and experience, using form RH 2000A or submit evidence of appropriate certification (see Appendix C).

b. **Authorized User(s) for Nonmedical Use**

These individuals should be listed as users for nonhuman use (e.g., animal studies, physical measurements only). For these individuals, forms RH 2000A or RH 2050A may be used to document and submit their training and experience information.

c. **Radiation Safety Officer**

If the Radiation Safety Officer is not one of the individuals named in Item 4, submit a complete description of their training and experience. Either form RH 2000A or RH 2050A may be used for this purpose.

The Radiation Safety Officer should be an employee of the licensee/applicant. If the licensee employs a consultant to assist the Radiation Safety Officer, the licensee is still responsible for the radiation safety program committed in the license.

**Item 10. Instrumentation.** Instruments required in a typical nuclear medicine laboratory are:

a. **Contamination and Survey Instruments**

- (1) For Group 1 and Group 2 (unit dosage) authorizations, a portable low-range survey meter with scales in cpm or mR/hr. This type of meter is usually of a GM tube (window thickness  $\leq 7 \text{ mg/cm}^2$ ) or NaI crystal detector and is used to detect microcurie amounts of radioactivity and the appropriate exposure levels.

When calibrated in mR/hr, these instruments usually have a deflection between 0.1 and 1.0 mR/hr on the most sensitive scale.

- (2) For multidose, Tc-99m generator and therapy procedures, a portable high-range dose rate meter is required, in addition to the survey meter noted above. This high-range meter must be an ion chamber or an energy-compensated GM and capable of reading up to 500 mR/hr (1R/hr for therapy) to allow for exposures rates that may exist in the vicinity of Tc-99m generators and therapeutic quantities of radioactive materials.

b. **Dose Calibrators**

All medical licensees are required to have in their possession a dose calibrator for use to measure the amount of radiopharmaceutical to be administered to a patient. All radiopharmaceuticals to be administered to patients must be assayed (immediately prior to administration) with an overall error not to exceed ten percent. For those licensees authorized the use of Molybdenum 99 (Mo-99)/Technetium 99m (Tc-99m) generators for preparing radiopharmaceuticals, the eluate must be assayed for Mo-99 content, and must contain no more than 0.15 microcuries per millicurie of Tc-99m at the time of

administration. No licensee may administer to humans any radiopharmaceutical containing more than 0.15 microcuries of Mo-99 per millicurie of Tc-99m. All eluates must also be assayed for aluminum ion content following the manufacturer's recommendations.

Records of all assays are required to be maintained for three years.

- c. **Diagnostic Instruments For All Approved Procedures** (e.g., gamma camera, well counter for Group 1 procedures, thyroid probe, etc.)
- d. **Other Pertinent Instrumentation** (e.g., liquid scintillation counter, area monitor, air sampler, velometer, etc.)

Appendix D to this guide provides a form that may be used to describe the instruments. Complete this form by listing the instruments to be used. If this form is not used, attach equivalent information. Check the appropriate box in item 10 of form RH 2000.

Guidance in the determination of appropriate instrumentation is available from the Department.

#### **Item 11. Calibration of Instruments**

- a. **Survey Instruments.** An adequate calibration of survey instruments cannot be performed with built-in check sources. Electronic calibrations that do not involve a source of radiation are also not adequate to determine the proper functioning and response of all components of an instrument.

Battery and constancy checks of survey instruments prior to each use shall be supplemented at least every 12 months with a two-point calibration on each scale of the instrument. One point should be in each half of the scale, and the two points should be separate by at least 50 percent of full scale. Survey instruments shall also be calibrated after repair or servicing (battery change is not considered as servicing, but a constancy check should be done after the change).

A survey instrument may be considered properly calibrated at one point when the exposure rate measured by the instrument differs from the true exposure rate by less than ten percent of full scale.

If you propose to calibrate your own radiation survey and monitoring instruments, submit a detailed description of your calibration facility, equipment, and calibration procedures. Include in the description:

- (1) The manufacturer's name and model number of the source(s) and device (if applicable) to be used. The source must be traceable by documented measurements to a standard certified to within five percent accuracy by the National Institute of Standards and Technology (NIST).
- (2) The nuclide and activity (in millicurie) of radioactive material contained in the environment in which the calibrated instrument will be used. The

activity should be such that the exposure rate at 100 cm is 30 mR/hr. Typical activities are 85 mCi for Cs-137 and 21 mCi for Co-60.

- (3) The step-by-step procedures, including associated radiation safety procedures. These procedures should include a two-point calibration of each scale of each instrument with the points separated by 35 to 50 percent of full scale.

If a consultant or outside firm will perform the calibration of your radiation survey and monitoring instruments, specify the name, address, and license number. The firm or consultant must be licensed to perform calibrations as a customer service.

Section 2 of Appendix E to this guide contains an acceptable procedure for calibrating survey instruments. Indicate, by checking the appropriate box in Item 11 of form RH 2000, if the procedure described in Appendix E will be followed. If the procedure in Appendix E is not followed submit equivalent procedures.

- b. **Dose Calibrator.** All photon-emitting radiopharmaceuticals greater than ten microcuries shall be assayed for activity to an accuracy of ten percent prior to administration into patients. The usual method for performing assays is with a dose calibrator. Upon installation and periodically thereafter, dose calibrators are to be tested for accuracy of response of the energies commonly used, for geometrical variation, for linearity of response over the entire range of activities to be used, and for day-to-day constancy of operation.

Submit a description of your calibration procedures. These should include as a minimum:

- (1) The manufacturer's name and model number of any sealed sources to be used.
- (2) The nuclide and activity (in millicuries) of radioactive material in the standards.
- (3) The accuracy of the standard.
- (4) The step-by-step procedures used for calibration.

If an instrument other than a dose calibrator is used to assay patient doses, submit a complete description of:

- (1) The assay method.
- (2) The method of calibration.
- (3) The frequency of calibration.
- (4) The standards to be used for calibration (radionuclide, activity, accuracy).

Section 3 of Appendix E contains a description of an acceptable procedure for calibrating dose calibrators. Indicate, by checking the appropriate box in Item 11 of form RH 2000, if the procedure in Appendix E for calibrating dose calibrators will be followed. If Appendix E is not followed, submit equivalent procedures.

- c. **Diagnostic Instruments** (imaging, uptake, well counter systems) The manufacturer's directions should be followed for calibration and maintenance of diagnostic instrumentation. Submit a description of your quality assurance program. For imaging equipment, the program should include daily peak and uniformity (intrinsic or extrinsic) tests, weekly resolution, linearity tests, and sensitivity calculations (cps/uCi). For those doing intrinsic uniformity tests, describe how collimator integrity is checked.

*For imaging equipment that has been transported, the daily checks must be performed at each location of use before administration of radiopharmaceuticals. An authorized user or designated technologist must approve the camera for use prior to administration of radiopharmaceutical (exceptions to this requirement may be granted by a license amendment).*

Section 4 of Appendix E contains acceptable procedures for calibrating imaging equipment (SPECT studies not included). If Appendix E is not followed, submit equivalent procedures.

If SPECT studies are performed, provide additional information relative to frequency and procedures for center of rotation verification, and uniformity correction flood matrix acquisition.

**Item 12. Facilities and Equipment** Describe the available facilities and equipment (e.g., remote handling equipment, storage containers, shielding, fume hoods, and filtration) at each location where radioactive material will be used or stored. Include a description of the area(s) assigned for receipt, storage, preparation, use of radioactive material, and storage of radioactive wastes.

Submit a diagram showing the locations of shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety. Indicate any wall shielding, special storage area shielding or movable shielding around storage areas, generators, kit preparation areas, etc.

For facilities in which radioactive material may become airborne, include schematic descriptions for the ventilation system in the diagrams with pertinent airflow rates, pressures, filtration equipment, and monitoring instruments. Airflow rates shall be tested at intervals not to exceed 12 months and following any repairs that affect the ventilation system.

A fume hood must be used for storage of therapeutic quantities of liquid form iodine and/or multidosage quantities of other gaseous or volatile radioactive materials. The hood must vent directly to the outside air and must have a linear face velocity of at least 100 feet per minute at the operating sash height. This face velocity shall be tested at intervals not to exceed 12 months and following any repairs that affect the ventilation system.

Mobile nuclear medicine licensees need only to submit facility sketch and description of their storage locations. Where a temporary job facility involves use of radioactive gas, the facility sketch and schematic descriptions of the ventilation system must be submitted. Figures 1 and 2 contain examples of acceptable facility and equipment descriptions.

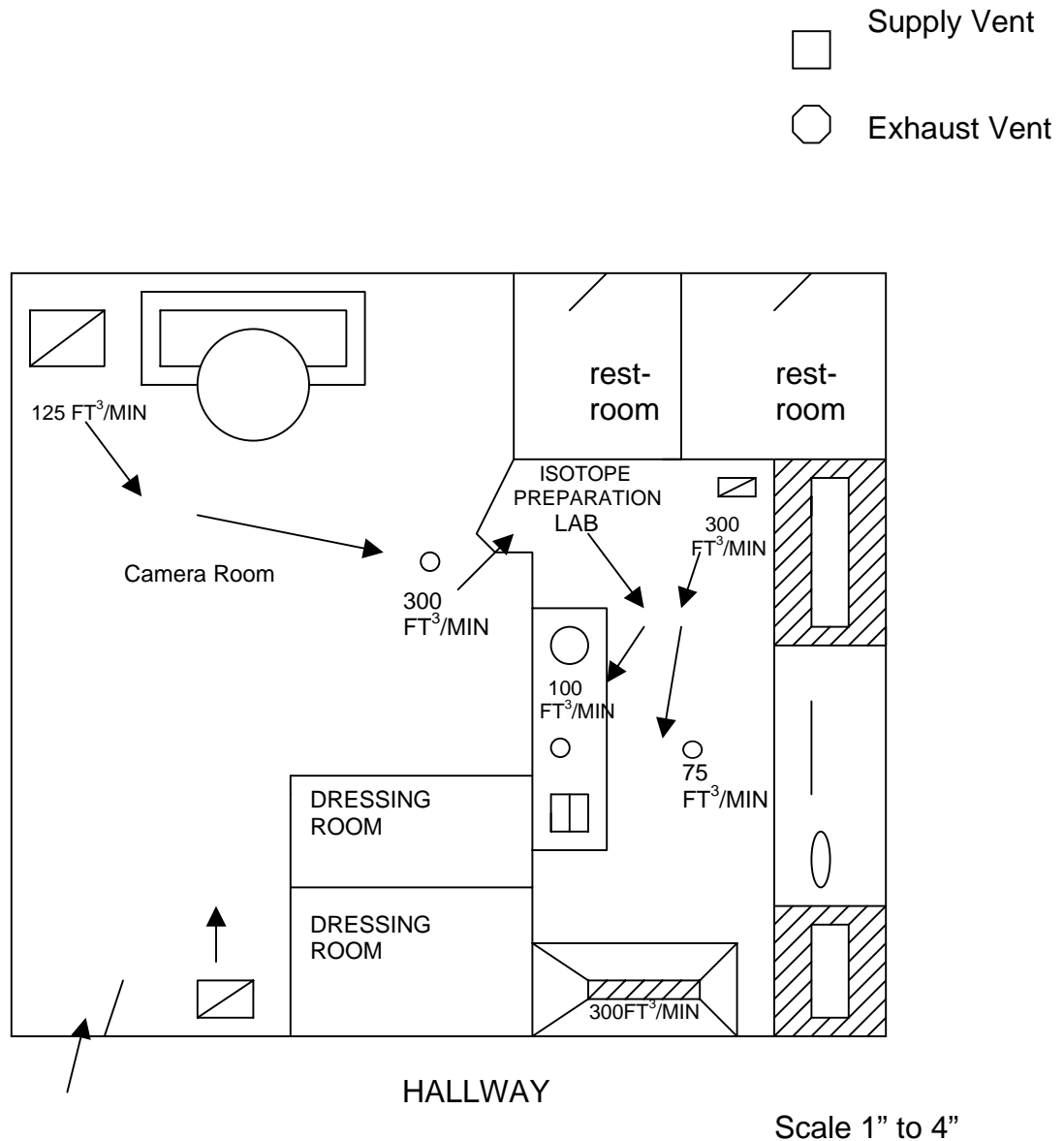


FIGURE 1.

EXAMPLE OF AN ACCEPTABLE TYPE OF LAYOUT DIAGRAM FOR  
A FACILITY DESCRIPTION INCLUDING VENTILATION FLOW RATES

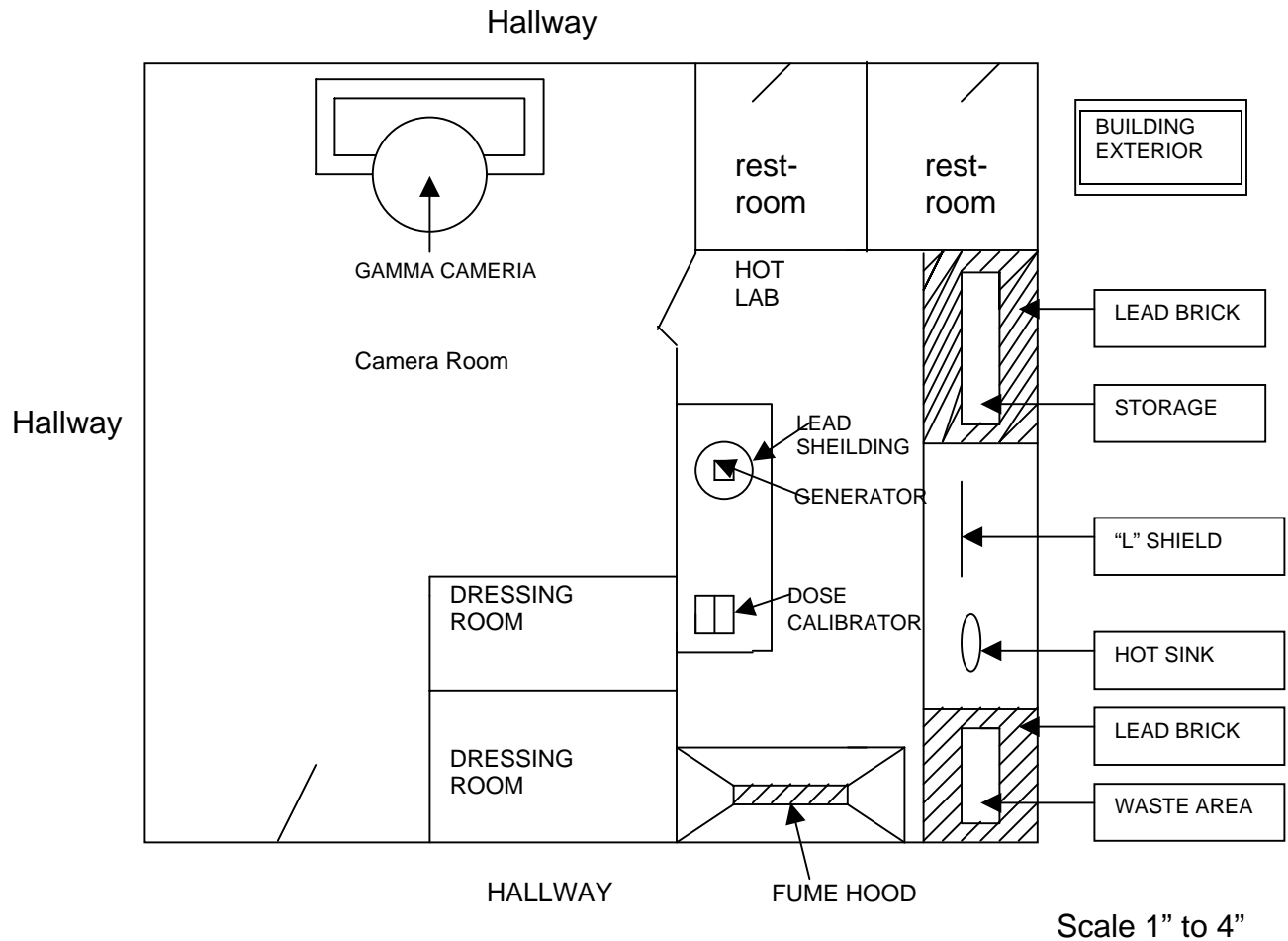


FIGURE 2.

EXAMPLE OF AN ACCEPTABLE TYPE OF LAYOUT DIAGRAM FOR  
A FACILITY DESCRIPTION INCLUDING SHIELDING PROVISIONS

**Item 13. Personnel Training Program.** Describe the radiation safety training required for all personnel who work with radioactive materials or work in the vicinity of areas where radioactive material is used or stored. Include the form of training (e.g., formal course work, lectures), frequency of training, duration of training, and subject matter. The training program shall be of sufficient scope to ensure that all personnel including technical, clerical, nursing, housekeeping, and security personnel, receive proper instruction including as appropriate:

- a. Areas where radioactive material is used or stored.
- b. Potential hazards associated with radioactive material.
- c. Radiological safety procedures appropriate to their respective duties.

- d. Pertinent California regulations.
- e. Rules and regulations of the licensee.
- f. Pertinent terms of the license.
- g. Their obligations to report unsafe conditions.
- h. Appropriate response to emergencies or unsafe conditions.
- i. Their right to be informed of their radiation exposure and bioassay results.
- j. Locations where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by Section 30280.
- k. Prenatal radiation exposure.
- l. Licensee's ALARA program.

Verify (appropriately documented) that personnel will be properly instructed.

- a. Before assuming duties with or in the vicinity of radioactive materials.
- b. During annual refresher training.
- c. Whenever there is a significant change in duties, regulations, or the terms of the license.

If the institution is a teaching hospital, the physicians training program must be described in detail. The names of physicians who will act as preceptors for residents in training should be specified. If residents will rotate to other hospitals as part of their training, the hospitals and the physicians at these hospitals who will act as preceptors should also be named.

**Item 14. Procedures for Ordering and Receiving Radioactive Material.** Describe procedures for ordering radioactive materials, for receiving materials during off-duty hours, and for notifying responsible persons upon receipt of radioactive materials. These procedures shall be adequate to ensure that possession limits are not exceeded, that radioactive materials for human use are adequately verified upon receipt and checked before use, that radioactive materials are secured at all times against unauthorized removal, and that radiation levels in uncontrolled areas do not exceed the limits specified in Section 30268.

Security personnel, nursing personnel, or anyone else who receives packages during off-duty hours shall be issued written instructions as to procedures to be followed for: receiving, examining, and securing the package; notification procedures if the package is found or suspected to be leaking; and the immediate steps to be taken to prevent spread of contamination.



Appendix F to this guide contains sample procedures and instructions for ordering and receiving packages containing radioactive material. Attach a copy of your procedures if Appendix F is not followed.

**Item 15. Procedures for Safely Opening Packages Containing Radioactive Materials.** Describe your procedures for examining incoming packages for leakage, contamination, or damage and for safely opening packages in accordance with Section 30282. Perform the monitoring as soon as practicable after receipt of the package of radioactive material. The procedures may vary depending on the quantity of radioactive material received but shall, as a minimum, include instructions for surveying packages, wearing gloves and dosimetry devices while opening packages, and checking packing materials for contamination after opening.

Appendix G to this guide contains a description of an acceptable procedure for safely opening packages. Indicate, by checking the appropriate box in Item 15 of form RH 2000, that the procedure in Appendix G will be followed or attach equivalent procedures.

**Item 16. Records of Possession and Use of Radioactive Material.** Describe your procedures for keeping records of prescription dosages and tests required to be performed before their use in humans. Records required here should include supplier, date received, chemical form or trade name, activity, lot number, and date of administration or disposal. If administered, the measured activity, patient name, and ID number.

Appendix H to this guide contains a description of an acceptable procedure to maintain inventory of radioactive materials and also ensure that tests required on prescription dosages are performed before use on humans. Indicate, by checking the appropriate box in Item 16 of form RH 2000, that the procedure in Appendix H will be followed or attach equivalent procedures.

**Testing for Leakage of Sealed Sources.** (Submit procedures if done in house.) A sealed or solid source shall be tested for leakage before first use unless the licensee has a certificate from the supplier indicating that the source was tested within six months before transfer to the licensee.

Each sealed or solid source shall be tested for leakage at intervals not to exceed six months unless excepted or varied by a license condition.

If tests are done in-house, the licensee must submit detailed information on procedures, instrumentation (including minimum detectable activity level), and dedicated check source traceable to a National Institute of Standards and Technology certified standard. Test wipes cannot be measured in a dose calibrator or with a survey meter since these instruments may not be sensitive enough to detect the presence of 0.005 microcuries of radioactive material on the sample. Normally a well-type (NaI) counter is necessary to assay gamma-emitting test samples.

A leak test service contractor may be used provided the contractor is approved to perform such service on an NRC or an Agreement State license.

**Item 17. General Rules for the Safe Use of Radioactive Material.** Describe the general instructions to be followed by physicians and technologists while working with radioactive materials. The instructions shall:

- a. Outline control procedures for obtaining permission to use radioactive material at the institution.
- b. Explain what laboratory apparel to wear and what equipment to use, e.g., wearing of laboratory coats and use of disposable gloves and trays.
- c. Prescribe limitations and conditions for handling liquid or loose radioactive materials and laboratory equipment to use in working with them. For example, specify which materials and operations should be confined to radiochemical fume hoods or glove boxes.
- d. Specify the shielding or remote handling equipment to be used when hard beta- and/or gamma-emitting materials are handled. Preparation of radiopharmaceuticals for reagent kits should be done behind shielding. Syringe shields should be used for the preparation and administration of patient doses.
- e. Give instructions for preparation and assay of patient dosages.
- f. Give instructions concerning movement of material between rooms, in halls, or in corridors if applicable.
- g. Explain requirements for storage of materials, labeling or containers, and identification of areas where radioactive materials are used or stored. Describe the shielding used for areas where large amounts of radioactive material are stored.
- h. Specify personnel monitoring devices to be used, where to obtain them, and instructions for recording exposure results or properly turning in personnel monitoring devices for processing at appropriate intervals.
- i. Describe waste disposal procedures to be followed for each type of waste (e.g., liquids, gases, solids, long-lived, short-lived).
- j. Describe contamination control procedures including prohibitions against smoking, eating, drinking, or applying cosmetics in restricted areas, and instructions for individuals who prepare dosages and radiopharmaceuticals to monitor their hands and protective clothing after each procedure and at the end of the day.

For smaller programs, Appendix I to this guide contains an acceptable set of laboratory rules for the safe use of radioactive materials. Indicate, by checking the appropriate box in Item 17 of form RH 2000, if Appendix I rules will be followed or attach equivalent procedures.

**Item 18. Area Survey Procedures.** Describe the routine survey program, including the areas to be surveyed, the levels of contamination considered to be acceptable, and provisions for maintaining records of survey.

If the application is to cover multiple users and areas of use, the individual user should perform surveys of their own work areas in addition to those performed by the radiation safety staff. Acceptable procedures and frequencies for routine surveys are described in Appendix J to this guide. Indicate, by checking the appropriate box in Item 18 of form RH 2000, that you will follow survey procedures in Appendix J or submit equivalent procedures.

**Item 19. Emergency Procedures.** Describe the emergency instructions to be posted in all laboratory areas where radioactive materials are used. These instructions should: (a) describe immediate action to be taken in order to prevent contamination of personnel and work areas (e.g., turning off the ventilation if appropriate, evacuation of the area, containment of the spill), (b) state the names and telephone numbers of the responsible persons to be notified in case of an emergency, and (c) instruct personnel on appropriate methods for re-entering, decontaminating, and recovering facilities that may have been accidentally contaminated.

An acceptable set of emergency procedures contained in Appendix K to this guide. Indicate, by checking the appropriate box in Item 19 of form RH 2000, that you will follow the emergency procedures in Appendix K or submit a copy of equivalent procedures.

**Item 20. Waste Disposal.** Describe specific methods used for disposal of radioactive waste. A licensee may dispose of radioactive material in waste by:

- a. Transfer to persons properly licensed to receive such material, e.g., commercial waste disposal firms (see Section 30285). Processing of wastes prior to transfer (e.g., by compaction) requires amendment to the license.
- b. Release into a sanitary sewer in conformance with Section 30287. Describe your methods for controlling the sewage disposals of radioactive waste in order to ensure that such disposals do not exceed the limits specified in Section 30287. Patient excreta and urine are not subject to these limits except when collected for analysis purposes.
- c. Holding for decay until radiation levels, as measured with a low-level survey meter and with all shielding removed, are not statistically significant as compared with background levels. With a low-range survey instrument, this is normally taken as twice the background count rate. All radiation labels must be removed or defaced prior to disposal in normal trash. (Note: this method is not permissible for low-energy beta emitters such as tritium, Carbon-14, and Sulfur-35 and is not practicable for long-lived radioactive material including generators containing long-lived radioactive contaminants.)
- d. Liquid scintillation media and animal carcasses containing 0.05 microcuries or radioactivity if the license submits procedures showing how the concentrations

will be determined and how the H-3 and C-14 media will be isolated from similar wastes containing other radionuclides.

NOTE: No licensee shall dispose of radioactive material waste by burial or incineration unless specifically authorized by the Department (see Sections 30288 and 30289). Volume reduction by compaction also requires approval from the Department.

Appendix L to this guide contains a form that maybe used to supply the information request in Item 20 of the application form. Indicate, by checking the appropriate box in Item 20 of form RH 2000, that you dispose of wastes as specified on the form in Appendix L or attach equivalent information.

**Item 21. Therapeutic Use of Radiopharmaceuticals.** Describe special precautions for patients treated with radioactive material listed in Groups 4 and 5 of RH 2010R (Well-Established Medical Uses). Although Group 4 procedures are often performed on an outpatient basis, hospitalization is sometimes required.

Establish appropriate procedures for therapeutic use of radioactive materials and include:

- a. Method for preparation and administration of therapeutic dosages of Iodine 131. Instruct personnel to wear gloves and to open containers of Iodine 131 in a fume hood with adequate airflow, to take other precautionary measures to prevent contamination of themselves and surrounding areas, and to prevent inhalation of the radioactive material.
- b. Methods for contamination control
  - (1) Assignment to private room
  - (2) Use of disposable items (e.g., dishes, utensils)
- c. Procedures for surveys of:
  - (1) Unrestricted areas
  - (2) Linens and other items removed from patient's room
  - (3) Patient's room before it is reassigned to another patient

(Licensees shall also performs surveys [e.g., measurement of Iodine 131 in air and/or measurement of Iodine 131 in the thyroid gland of laboratory personnel; contamination surveys of personnel, equipment, and facilities) to determine compliance with Sections 30265 through 30269.)
- d. Instructions to nursing staff
- e. Procedures for disposal of waste
  - (1) Patient excreta
  - (2) Surgical dressings
  - (3) Disposable items

- f. Procedures to be followed in case of emergency surgery or death
- g. Procedures for release of patients

(1) Criteria for release of patients

Patients treated with Iodine 131 may be released without restrictions when the patient contains eight millicuries or less.

If Iodine-131 content is between 8 and 30 millicuries, oral and written radiation safety precautions shall be provided to the patient prior to discharge.

Above 30 millicuries, a patient shall be released only upon approval by the Department, and with notification of the local health authorities.

(2) Radiation safety instructions to patients and families.

- h. Procedures for determining external radiation doses to attending personnel (e.g., nurses).
- i. Procedures for evaluating thyroid uptakes of personnel. Significant thyroid uptakes have been detected in individuals who prepare and handle therapeutic quantities of iodine (see Item 25).

References for the management of therapy patients may be found in the Technical Reports section.

Appendix M to this guide contains a description of precautions to be followed for patients treated with Iodine 131 or Phosphorus 32. Indicate, by checking the appropriate box in Item 21 of form RH 2000, that you will follow Appendix M procedures or submit equivalent procedures. Also submit detailed response to Item 21(a).

**Item 22. Therapeutic Use of Sealed Sources.** Describe special procedures for patients treated with radioactive materials listed in Group 6 of RH 2010R. These procedures shall include descriptions of:

- a. The areas where sealed sources will be stored, including (1) placement and thickness of shielding and (2) proximity of the storage area to unrestricted areas. Also, describe the treatment room(s).
- b. Special precautions to be used while handling sealed sources.
- c. Special instructions for nursing care of patients who are treated with sealed sources. (Appendix N to this guide contains a description of procedures to be followed by patients treated with sealed sources.)
- d. Your method for determining the radiation doses to the extremities of personnel handling sealed sources and radiation doses to attending personnel (e.g., nurses, residents).

- e. The equipment and shielding available for transporting sources from storage sites to the place of use.
- f. Your method for maintaining source accountability at all times. This should include a description of sign-in and sign-out procedures, periodic inventory, and the method for determining that all sources are accounted for and returned to storage following treatment (see Exhibit 7).
- g. Surveys to be performed during the course of treatment and at the conclusion of treatment. The patient and room shall be surveyed with a radiation survey instrument after the end of treatment and before dismissal. Your dismissal survey shall include a source count and must be adequate to determine that all temporary implant sources have been removed from the patient and from all areas that the patient occupied.
- h. Specific precautions to be taken if you plan to reuse Iodine-125 seeds. The procedures shall provide for removal/reloading operation in a fume hood, and performing wipe surveys of tools and work area, or leak testing the seeds following removal, and reloading operations.

Submit detailed responses to 22. a, b, d, e, f, g, and h above. In response to 20. c, indicate that the procedures described in Appendix N will be followed or submit equivalent procedures.

**Item 23. Procedures and Precautions For Use of Radioactive Gases of Aerosols** (e.g., Xenon-133). The storage and use of radioactive gases (e.g., Xenon-133 gas or gas in saline) require attention not only to the standard radiation safety considerations but also to an evaluation of expected air concentrations of the radioactive gas in restricted and unrestricted areas. The Department requires that each applicant make such determinations for their own unique situation and submit sufficient evidence in support of their request. The applicant must describe storage provisions.

Appendix O to this guide contains instructions for submitting an application to use radioactive gases. The information requested in Appendix O should be submitted.

**Item 24. Procedures and Precautions For Use of Radioactive Materials in Animals or In Vitro Studies.** For animals, describe procedures to be followed if radioisotopes will be used in animals including (a) a description of the animal housing facilities, (b) a copy of instructions provided to animal caretakers for the handling of animals, animal waste, and carcasses, (c) instructions for cleaning and decontaminating animal cages, and (d) procedures for ensuring that animal rooms will be locked or otherwise secured against unauthorized entry.

For in vitro studies, provide information on additional facilities (if applicable) and equipment. Clearly state any additional radiation safety procedures to be followed while individuals are working with radioactive materials (e.g., air sampling, other special surveys, bioassays).

## **Item 25. Personnel Monitoring**

### ***External Exposure Monitoring Devices***

Licensees wishing to have the flexibility of choice should indicate that an NVLAP-certified dosimetry service provider will be used. Others should state the name of the organization furnishing film badges or thermoluminescent dosimeter (TLD) service.

Specify the frequency with which the devices are exchanged and evaluated, and give a description of the type, e.g., whole-body, wrist, or finger badge. Where wrist badges are worn to monitor extremity exposures and exposures to fingertips are likely to be greater than the wrist exposures, describe how fingertip exposures will be estimated from the wrist badge data in lieu of fingertip monitors, and provide any back-up data used to perform or verify these estimates.

### **Internal Update Evaluation**

Licensees using therapeutic quantities of iodine are required to employ suitable measures for detecting and evaluating airborne radioactivity in controlled areas and, as appropriate, use measurements of radioactivity in the body, excreta, urine, or any combination of such measurements to detect and assess individual intakes of radioactive materials by exposed individuals.

The above requirement may be met by developing a comprehensive bioassay program that incorporates participation criteria, uptake action (investigation) level, frequency of evaluation, instrumentation, and pertinent quality assurance checks. The Department may stipulate bioassay frequency as a license condition.

Licensees handling therapeutic quantities of Iodine 131 must submit a bioassay program or an alternative method of assessing internal uptake of laboratory personnel. Air sampling may be an acceptable alternative.

Licensees using only capsules may be exempted from the uptake assessment requirement if they submit detailed procedures of how the capsules are stored and handled. Such procedures shall include opening capsule containers in a fume hood and using appropriate source handling tools.

If the licensee wishes to use outside services for its bioassay program, the vendor's instrumentation and quality assurance program must be submitted unless these are already on file with the Department.

## **Item 26. (*For Private or Group Practice Applicants Only*)**

**Item 26.a.** State the name and address of the hospital that has agreed to admit patients in need of hospitalization after undergoing nuclear medicine procedures.

**Item 26.b.** Submit a copy of the letter of authorization, signed by the administrator, from the hospital that has agreed to admit patients described in 26.a above.

**Item 26.c.** If patients treated with therapeutic quantities under this license are admitted to the hospital: (1) describe the radiation detection instruments available at the hospital, and (2) submit a copy of the radiation safety procedures to be followed.

**Item 27. Certification.** Provide the signature of an individual authorized by management to represent the institution or the signature of the physician (in case of licenses issued to clinics or individual physicians) and the date of signature.

This individual must be in a position of legal and financial responsibility to the applicant.

## **5. AMENDMENTS TO LICENSES**

Licensees are required to conduct their programs in accordance with statements, representations, and procedures contained in the license application and supporting documents. The license must be amended if the licensee plans to make any changes in the facilities, equipment (including types of monitoring and survey instruments), procedures, or types of radioactive material to be used which significantly impact the radiation safety program. Amendment must be requested for all changes in authorized users, the Radiation Safety Officer, chairperson of the medical Radiation Safety Committee, custodian of sealed sources, and physicians responsible for research and IND authorizations.

Applications for license amendments may be requested on the application form, RH 2000 or by letter, and must clearly describe the exact nature of the changes, additions, or deletions. References to previously submitted information and documents must be clear and specific and must identify the pertinent information by date, page, and paragraph. An original and two copies of the application for amendment should be prepared, and the original and one copy must be submitted (as done for new or renewal applications). See Appendix P for commonly requested amendments.

## **5. RENEWAL OF A LICENSE**

An application for renewal of a license must be filed at least 30 days prior to the expiration date. This will ensure that the license does not expire until final action on the application has been taken by the Department as provided for in Section 30198. *Failure to submit a timely renewal will subject the license to expire prior to Department action. The license must therefore stop all uses of radioactive materials and divest, or place into safe storage all radioactive materials in their possession.*

Renewal applications must be filed on form RH 2000 and appropriately supplemented, and must contain complete and up-to-date information about the applicant's current program, and must also meet all licensing and regulatory requirements in effect at the time of renewal. Renewal applications should also include the user physicians' training and experience (RH 2000A) or make a clear and specific reference to previous applications on which individual users received approval.



In order to facilitate the review process, the application for renewal should be submitted without reference to previously submitted documents and information (except for previously approved users).

Prepare an original and two copies of the application. Retain one copy of the application, with all attachments, because the license will require, as a condition, that the institution follow the statements and representations set forth in the application and any supplement to it. Mail the original and one copy to:

State of California  
Department of Health Services  
Radiologic Health Branch  
714/744 P Street, MS 178  
P.O. Box 942732  
Sacramento, CA 94234-7320

## APPENDIX A

### PROGRAM FOR MAINTAINING RADIATION EXPOSURE AT MEDICAL INSTITUTIONS (ALARA)

(See Section 30253 of Title 17)

The term ALARA is an acronym for maintaining radiation exposures, and effluent releases of radioactive material in uncontrolled areas “as low as reasonably achievable” taking into account the available technology, economic costs in relation to benefits to the public health and safety, and other societal and socioeconomic considerations in their relationship with the utilization of radioactive materials and radiation-producing equipment in the public interest.

The ALARA philosophy extends to exposure to individuals in the performance of their duties and to patients undergoing medical evaluations and treatments.

To achieve this goal, the management should address dose reduction for both workers and patients.

Although the model presented here is developed specifically for occupational exposure considerations, management should incorporate into their program those procedures, practices, and quality assurance checks that can eliminate unnecessary or extraneous radiation exposures to patients without compromising the quality of medical service. Such practices and checks include, but are not limited to:

- a. Use of appropriate and well-calibrated instrumentation and equipment.
- b. Use of appropriate films and good processing techniques.
- c. Use of organ shields in diagnostic radiology.
- d. Staying with the well-established dosage limits unless deviation is absolutely essential in the judgment of the responsible physician.

#### 1. **Management Commitment**

- a. We, the management of this (*insert name of medical facility, hospital, etc.*), are committed to an efficient medical use of radioactive materials and radiation producing equipment by limiting their use to clinically operated radiation equipment; limiting dosages to those recommended by the manufacturer unless otherwise necessary, using calibrated diagnostic and related instrumentation; and using appropriately trained personnel.
- b. We commit to the program described below for keeping occupational individual and collective doses ALARA. Toward this commitment, we hereby describe an administrative organization for radiation safety and will develop all necessary written policy, procedures, and instruction to foster the ALARA philosophy within our institution. The organization will include

- a Radiation Safety Committee (RSC) and a Radiation Safety Officer (RSO).
- c. We will perform a formal annual review of the radiation safety program, including ALARA considerations. The review will cover operating procedures and past dose records, inspections, and recommendations of the radiation safety staff or consultants.
- d. We will modify operating and maintenance procedures, equipment, and facilities if these modifications will reduce exposures and the cost is justified.

## 2. **Radiation Safety Committee**

### a. **Review of Proposed Users and Uses**

- (1) The RSC will thoroughly review the qualifications of each applicant with respect to the types and quantities of radioactive materials and radiation-producing equipment and methods of use for which application has been made, to ensure that the applicant will be able to take appropriate measures to maintain exposure ALARA.
- (2) When considering a new use of radioactive material or radiation-producing equipment, the RSC will review the efforts of the applicant to maintain exposure ALARA.
- (3) The RSC will ensure that the users justify their procedures and that individual and collective doses will be ALARA.

### b. **Delegation of Authority**

(The judicious delegation of RSC authority is essential to the enforcement of an ALARA program.)

- (1) The RSC will delegate authority to the RSO for enforcement of the ALARA program.
- (2) The RSC will support the RSO when it is necessary for the RSO to assert authority. If the RSC has overruled the RSO, it will record the basis for its action in the minutes of the quarterly meeting.

### c. **Review of ALARA Program**

- (1) The RSC will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.
- (2) The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances in which the investigational levels in Table 1 are exceeded. The principal

purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when investigational levels are exceeded (see Section 5 below for a discussion of investigational levels).

- (3) The RSC will evaluate the institution's overall efforts for maintaining doses ALARA on an annual basis. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

**Table 1**  
**Investigational Levels\***

	<b>Investigational Levels (mrems per calendar quarter)</b>	
	<b>Level I</b>	<b>Level II</b>
1. Whole body; head and trunk; active blood-forming organs; lens of eyes; or gonads.	125	375
2. Hands and forearms; feet and ankles	1,875	5,625
3. Skin of whole body	750	2,250
4. Thyroid uptake	0.1 microcurie	0.3 microcurie

\* Note that investigational levels in this program are not new dose limits but serve as checkpoints above which the results are considered sufficiently important to justify investigations. See Section 5 for further discussion.

### 3. **Radiation Safety Officer**

#### a. **Annual and Quarterly Review**

- (1) **Annual review of the radiation safety program.** The RSO will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific methods of use may be conducted on a more frequent basis.
- (2) **Quarterly review of occupational exposures.** The RSO will review at least quarterly the radiation doses of authorized users and workers to determine that their doses are ALARA in accordance with the provisions of Section 5 of this program and will prepare a summary report for the RSC.
- (3) **Quarterly review of records of radiation surveys.** The RSO will review radiation surveys in unrestricted and restricted areas to determine that dose rates and amounts of contamination were at ALARA levels during the previous quarter and will prepare a summary report for the RSC.

**b. Education Responsibilities for ALARA Program**

The RSO (in cooperation with authorized user) will ensure that radiation workers and, as applicable, ancillary personnel are trained and educated in good health physics practices and procedures.

- (1) The RSO will schedule briefings and educational sessions to inform workers of the ALARA program efforts.
- (2) The RSO will ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that management, the RSC, and the RSO are committed to implementing the ALARA concept.

**c. Cooperative Efforts for Development of ALARA Procedures**

- (1) Radiation workers will be given opportunities to participate in formulating the procedures that they will be required to follow.
- (2) Radiation workers will be instructed in recourses that may be taken if they feel that ALARA is not being promoted in the workplace.

**d. Reviewing Instances of Deviation From Good ALARA Practices**

The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO will implement changes in the program to maintain doses ALARA.

**4. Authorized Users**

**a. New Methods of Use Involving Potential Radiation Doses**

- (1) The authorized user will consult with the RSO and/or RSC during the planning stage before using radioactive materials and radiation-producing equipment to ensure that doses will be kept ALARA. Simulated trial runs may be helpful.
- (2) The authorized user will review each planned use of radioactive materials or radiation-producing equipment to ensure that doses will be kept ALARA. Simulated trial runs may be helpful.

**5. Establishment of Investigational Levels in Order to Monitor Individual Occupational Radiation Doses (External and Internal)**

This institution hereby establishes investigational levels for occupational radiation doses which, when exceeded, will initiate review or investigation by the RSC and/or the RSO. The investigational levels that we have adopted are listed in Table 1. These levels apply to the exposure of individual workers. The following actions will be taken at the investigational levels stated in Table 1.

a. **Personnel Dose Less Than Investigational Level I**

Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual dose is less than Table 1 values for the Investigational Level I.

b. **Personnel Dose Equal to or Greater Than Investigational Level I But Less Than Investigational Level II**

The RSO will review the dose of each individual whose quarterly dose exceeds Investigational Level I and will report the results of the reviews at the first RSC meeting following the quarter when the dose was recorded. If the dose does not equal or exceeds Investigational Level II, no specific action related to the exposure is required unless deemed appropriate by the Committee. The Committee will, however, review each such dose in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review in the Committee minutes.

c. **Personnel Dose Equal to and Greater Than Investigational Level II**

The RSO will investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation and any actions taken will be presented to the RSC at its first meeting following completion of the investigation. The details of these reports will be included in the RSC minutes.

d. **Reestablishment of Investigational Levels to Levels Above Those Listed in Table 1**

In cases where a worker's or a group of worker's doses need to exceed an investigational level, a new, higher investigational level may be established for that individual or group on the basis that it is consistent with good ALARA practices. Justification for new investigational levels will be documented.

The RSC will review the justification for and must approve or disapprove all revisions of investigational levels.

## **APPENDIX B**

### **MEDICAL RADIATION SAFETY COMMITTEE**

#### **Responsibility**

The committee is responsible for:

1. Ensuring that all individuals who work with or in the vicinity of radioactive material or radiation machines have sufficient training and experience to enable them to perform their duties safely and in accordance with California regulations and the conditions of the license.
2. Ensuring that all uses of radioactive material and of radiation machines are conducted in a manner consistent with ALARA philosophy and in accordance with California regulations and the conditions of the license.

#### **Duties**

The committee shall:

1. Be familiar with all pertinent California regulations, the terms of the license, and information submitted in support of the request for the license and its amendments.
2. Review the licensee's ALARA program.
3. Review the training and experience of any individual who uses radioactive material or radiation machines (including physicians, physicists, and pharmacists) and determine that the qualifications are sufficient to enable them to perform their duties safely and in accordance with California regulations and the conditions of the license.
4. Establish a program to ensure that all individuals whose duties may require them to work in the vicinity of radioactive material or radiation machines (e.g., nursing, security, and housekeeping personnel) are properly instructed as required by Section 30280.
5. Review and approve all requests for use of radioactive material within the institution prior to forwarding the request to the Department.
6. Prescribe special conditions that will be required during a proposed use of radioactive material or radiation machines such as requirements for bioassays, physical examinations of users, and special monitoring procedures.
7. Review and approve or disapprove, with advice and consent of the Radiation Safety Officer and the management representative, minor changes in radiation safety procedures.

8. Review quarterly, with the assistance of the Radiation Safety Officer, a summary of all radiation dose records and all incidents involving radioactive materials and radiation-producing equipment with respect to cause and corrective actions.
9. Establish a table of investigational levels of individual occupational radiation exposures.
10. Review the entire radiation safety program at least annually to determine that all activities are being conducted safely and in accordance with California regulations and the conditions of the license. The review shall include an examination of all records, reports from the Radiation Safety Office, results of California inspection, written safety procedures, and management control system.
11. Recommend remedial action to correct any deficiencies identified in the radiation safety program.
12. Maintain written records of all committee meetings, actions, recommendations, and decisions.
13. Ensure that the radioactive material license is amended, when necessary, prior to any changes in facilities, equipment, policies, procedures, and personnel.

### **Meeting Frequency**

The Radiation Safety Committee shall meet as often as necessary to conduct its business but not less than once in each calendar quarter. To establish a quorum, at least one-half of the committee membership must be present, including the Radiation Safety Officer.



## APPENDIX C

### ACCEPTABLE TRAINING AND EXPERIENCE FOR MEDICAL USES OF RADIOACTIVE MATERIAL

Section 30195 (a) of the California Radiation Control Regulations provides that the Department will approve a license application by an institution for medical use of radioactive material if it determines, among other things, that the physicians designated as authorized users are adequately trained and experience in (1) basic radionuclide handling techniques and (2) the clinical uses of radioactive material proposed in the application. Similar criteria are established in Section 30195 (b) for approval of licenses for medical use of radioactive material by individual physicians. Outlined below are training and experience criteria that the Department has found acceptable for physicians who use radioactive material. Each physician's training and experience are examined on a case-by-case basis. If a physician wishes to use radioactive material but does not have the training or experience described, they may submit an application listing their specific qualifications and these will be reviewed by the Department with the assistance of the Medical Advisory Committee.

1. **Group 1—Training Requirements for Uptake, Dilution, or Excretion Studies, But Not Involving Imaging**

To qualify as adequately trained to use or directly supervise the use of radioactive material listed in Group 1 of the Well-Established Uses List (RH 2010R), a physician should have:

- a. Training in basic radionuclide handling techniques (40 hours) consisting of lectures, laboratory sessions, discussion groups, and supervised experience in a nuclear medicine laboratory in the following areas:
  - (1) Radiation physics and instrumentation.
  - (2) Radiation protection.
  - (3) Mathematics, statistics, and computer sciences pertaining to the use and measurement of radioactivity.
  - (4) Radiation biology.
  - (5) Radiopharmaceutical chemistry.
- b. Supervised clinical training and experience under the supervision of an authorized user (20 hours). The clinical training should cover all appropriate types of diagnostic procedures and should include:
  - (1) Supervised examination of patients to determine the suitability for radionuclide diagnosis and recommendation on dosage to be prescribed.

- (2) Collaboration in calibration of the dose and actual administration of the dose to the patient, including calculation of the radiation dose, related measurement, and plotting data.
- (3) Supervised interpretation of results of radionuclide diagnostic procedures and follow up of patients when required.
- (4) Study and discussion with the preceptor of case histories to establish most appropriate diagnostic procedures, limitations, contraindications, etc.

#### **Note A**

For each physician named in item 4 of form RH 2000, complete form RH 2000A (preceptor statement and the statement of training in basic radioisotope handling techniques). For each subject covered in basic training, state where the training was obtained and the dates, total number of hours, and type of training (e.g., lectures, laboratory sessions).

#### **Alternatives**

Certification by the American Board of Nuclear Medicine or by the American Board of Radiology in Diagnostic Radiology (Diagnostic Radiology with Special Competence in Nuclear Radiology if prior to July 1984), or by the American Osteopathic Board of Radiology in Diagnostic Radiology or Radiology, or completion of a residency program in Nuclear Medicine that is approved by the Accreditation Council on Graduate Medical Education will be accepted as meeting the training and experience requirements for use of Group 1. Copies of certificates may be submitted in lieu of form RH 2000A. (See Section 8 for recentness of training.)

## **2. Groups 1, 2, and/or 3—Training Requirements for Imaging and Localization Studies and/or the Use of Generators and Reagent Kits for Preparation of Radiopharmaceuticals**

To qualify as adequately trained in use or directly supervise the use of radioactive material listed in Groups 1, 2, and/or 3 of the Well-Established Medical Uses List (RH 2010R), a physician should have:

- a. Training in basic radionuclide handling techniques (200 hours) consisting of lectures, laboratory sessions, discussion groups, and supervised experience in a nuclear medicine laboratory in the following areas:
  - (1) Radiation physics and instrumentation 100 hours
  - (2) Radiation protection 30 hours

- |     |  |          |
|-----|--|----------|
| (3) | Mathematics, statistics, and computer sciences<br>pertaining to the use and measurement of radioactivity | 20 hours |
| (4) | Radiation biology  | 20 hours |
| (5) | Radiopharmaceutical chemistry  | 30 hours |

(The hours listed for each of the subjects above are suggested values and should not be interpreted as specific requirements.)

- b. Supervised clinical training and experience under the supervision of an authorized user (500 hours). The clinical training should cover all appropriate types of diagnostic procedures and should include:
  - (1) Supervised examination of patients to determine the suitability for radionuclide diagnosis and recommendation on dosage to be prescribed.
  - (2) Collaboration in the calibration of the dose and the actual administration of the dose to the patient, including calculation of the radiation dose, related measurement, and plotting data.
  - (3) Supervised interpretation of results of radionuclide diagnostic procedures and follow up of patients when required.
  - (4) Study and discussion with preceptor of case histories to establish most appropriate diagnostic procedures, limitation, contraindication, etc.
- c. Supervised work experience under the supervision of an authorized user (500 hours). The experience should include:
  - (1) Ordering, receiving, and performing precautionary checks and measurements on radioactive packages.
  - (2) Quality assurance tests on dose calibrators, diagnostic instruments, and survey equipment.
  - (3) Elution of Technetium 99m from generators, testing for molybdenum and alumina contamination, and preparing radiopharmaceuticals with reagent kits.
  - (4) Radioactive spillage containment and decontamination procedures.
  - (5) Administration procedures to prevent misadministration of radiopharmaceuticals.

## **Note A**

It is not expected that the requirements specified in Sections 2.a, b, and c could be satisfied in less than a six-month training program.

## **Note B**

For each physician named in item 4 of form RH 2000, complete form RH 2000A (preceptor statement and the statement of training in basic radioisotope handling techniques). For each subject covered in basic training, state where the training was obtained and the date, total number of hours, and type of training (e.g., lectures, laboratory sessions).

## **Alternatives**

Certification by the American Board of Nuclear Medicine or by the American Board of Radiology in Diagnostic Radiology (Diagnostic Radiology with Special Competence in Nuclear Radiology if prior to July 1984), or by the American Osteopathic Board of Radiology in Diagnostic Radiology or Radiology, or completion of a residency program in Nuclear Medicine that is approved by the Accreditation Council on Graduate Medical Education will be accepted as meeting the training and experience requirements for use of Groups 1 and 3. Copies of certificates may be submitted in lieu of form RH 2000A. (See Section 8 for recentness of training.)

### **3. Groups 4 and 5—Training Requirements for Therapy Procedures Involving Radiopharmaceuticals**

A physician who is qualified to use radioactive material listed in Groups 1 and 3 and/or 6, RH 2010R, may also qualify to use or directly supervise the use of radioactive material listed in Groups 4 and/or 5 by submitting evidence of clinical training and experience in specific therapy procedures. (Physicians certified by the American Board of Nuclear Medicine need not submit this information.)

#### **a. For Group 4**

- (1) Iodine 131 for treatment of hyperthyroidism:

Clinical experience in the diagnosis of thyroid function and active participation in the treatment of ten patients.

- (2) Phosphorus 32 for treatment of polycythemia vera, leukemia, and/or bone metastases:

Treatment of three patients with any combination of the above three conditions.

- (3) Colloidal Phosphorus 32 intracavity treatment:

Active participation in the treatment of three or more patients.

**b. For Group 5**

- (1) Iodine 131 for treatment of thyroid carcinoma:

Clinical experience in diagnosis of thyroid function and treatment of hyperthyroidism and active participation in the treatment of three or more patients with thyroid carcinoma.

**4. Training Requirement For Use of Iodine 131 for Treatment of Hyperthyroidism/Thyroid Carcinoma Only**

To qualify as adequately trained to use or directly supervise only the use of Iodine 131 for the treatment of hyperthyroidism/thyroid carcinoma in Groups 4 and/or 5, the physician should have special experience in thyroid diseases and should have:

- a. Training in basic radionuclide handling techniques (80 hours) consisting of lectures, laboratory sessions, discussion groups, and supervised clinical experience in the following areas:

(1) Radiation physics and instrumentation	25 hours
(2) Radiation protection	25 hours
(3) Mathematics, statistics, and computer sciences pertaining to the use and measurement of radioactivity	10 hours
(4) Radiation biology	20 hours

(The hours listed for each of the subjects above are suggested values and should not be interpreted as specific requirements.)

- b. Clinical training and experience in the diagnosis of thyroid function, and active participation in the treatment of ten or more patients with hyperthyroidism and three or more patients with thyroid carcinoma.

**5. Groups 6 and 8—Training Requirements for Therapy Procedures Involving Sealed Sources**

To qualify as adequately trained to use or directly supervise the use radioactive material listed in Group 6, RH 2010R, a physician must be in active practice of therapeutic radiology and should have:

- a. Training in basic radionuclide handling techniques (200 hours) consisting of lectures, laboratory sessions, discussion groups, and supervised experience in the following areas:
  - (1) Radiation physics and instrumentation 100 hours
  - (2) Radiation protection 40 hours
  - (3) Mathematics, statistics, and computer sciences pertaining to the use and measurement of radioactivity 40 hours
  - (4) Radiation biology 20 hours

(The hours listed for each of the subjects above are suggested values and should not be interpreted as specific requirements.)
- b. Three years of supervised clinical experience that includes one year in a formal residency training program that is either approved for therapeutic radiology by the Accreditation Council on Graduate Medical Education or for radiation oncology by the American Osteopathic Association. The remaining two years should be spent under supervision of an authorized user in an institutional radiation therapy program, and the experience should include:
  - (1) Supervised examination of patients and their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications.
  - (2) Collaboration with the preceptor in selecting proper brachytherapy sources and doses, dose calculations, and method of administration.
  - (3) Collaboration with the preceptor in postadministration follow-ups.
- c. Supervised work experience in an institutional radiation therapy program (500 hours). The experience should include:
  - (1) Ordering, receiving, and performing precautionary checks and measurements on radioactive packages.
  - (2) Checking survey meters for proper operation.
  - (3) Preparing, implanting, and removing sealed sources from the patient.
  - (4) Using administrative controls to maintain inventory of sealed sources, and to prevent misadministrations.
  - (5) Reviewing full calibration measurements and periodic spot checks if request is for teletherapy.

- (6) Preparing treatment plans and calculating treatment times.
- (7) Familiarity with emergency procedures for controlling radiation exposures during radionuclide incidents.

### **Alternatives**

For use of radioactive material in Groups 6 and 8, evidence of certification by the American Board of Radiology in Therapeutic Radiology or Radiation Oncology, or certification by the American Osteopathic Board of Radiology in Radiation Oncology, or certification as a British "Fellow of the Faculty of Radiology" (FFR) or "Fellow of the Royal College of Radiology" (FRCR), or a Canadian certification in Therapeutic Radiology by the Canadian Royal College of Physicians and Surgeons (RCPS), or completion of a residency program in therapeutic radiology that is accredited by the Accreditation Council on Graduate Medical Education or Committee on Postdoctoral Training on the American Osteopathic Association may be submitted in lieu of form RH 2000A.

British certificates in Radiology must be accompanied by evidence of specialization in radiotherapy. (See Section 8 for recentness of training.)

## **6. Training Requirements for Therapy Procedures Involving SR-90, Ophthalmic Eye Applicators Only**

To qualify as adequately trained to use or directly supervise the use of SR-90 eye applicators, a physician must be in active practice of therapeutic radiology or ophthalmology and should have:

- a. Training in basic radionuclide handling techniques (24 hours minimum) consisting of lectures, laboratory sessions, discussion groups, and supervised experience in the following areas:
  - (1) Radiation physics and instrumentation 6 hours
  - (2) Radiation protection 6 hours
  - (3) Mathematics pertaining to the use and measurement of radioactivity 4 hours
  - (4) Radiation biology 8 hours

(The hours listed for each of the subjects above are suggested values and should not be interpreted as specific requirements.)

- b. Supervised clinical training and experience in an institutional ophthalmic radiotherapy program. The clinical training should include active participation in the treatment of five or more individuals which includes:
  - (1) Examination of each individual to be treated
  - (2) Calculation of the dose to be administered
  - (3) Administration of the dose
  - (4) Follow up and review of each individual's case history

#### **Alternatives**

Certification by the American Board of Radiology in Therapeutic Radiology or Radiation Oncology may be submitted in lieu of form RH 2000A.

### **7. Group 7—Training Requirements For Use of Sealed Sources For Diagnosis**

To qualify as adequately trained to use or directly supervise the use of sealed sources in devices listed in Group 7, a physician, dentist, or podiatrist should have:

- Eight hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device to include:
  - (1) Radiation physics, mathematics relative to the use and measurement of radiation, and instrumentation
  - (2) Radiation protection
  - (3) Radiation biology
  - (4) Training in the use of the device for the uses requested

#### **Alternatives**

Certification by the American Board of Radiology in Diagnostic Radiology or Therapeutic Radiology or Radiation Oncology, or by the American Osteopathic Board of Radiology in Diagnostic Radiology or Radiology, or by the American Board of Nuclear Medicine. A physician who is specifically named as an authorized user for one or more of Groups 1 through 6 may also be accepted as meeting the training requirements for Group 7.

### **8. Recentness of Training**

The training and experience specified in this appendix must have been obtained within the five years preceding the date of application. Failing to meet this requirement, the individual must provide evidence of continuing education and experience since training and experience were completed.



**APPENDIX D**  
**INSTRUMENTATION**

**1. Contamination survey meters (a)/dose rate meters (b)**

a. Manufacturer's name: \_\_\_\_\_

Manufacturer's model number: \_\_\_\_\_ (with model \_\_\_\_ probe)

Number of instruments available: \_\_\_\_\_

Minimum range: \_\_\_\_\_ mr/hr to \_\_\_\_\_ mr/hr

Maximum range: \_\_\_\_\_ mr/hr to \_\_\_\_\_ mr/hr

b. Manufacturer's name: \_\_\_\_\_

Manufacturer's model number: \_\_\_\_\_ (with model \_\_\_\_ probe)

Number of instruments available: \_\_\_\_\_)

Minimum range: \_\_\_\_\_ mr/hr to \_\_\_\_\_ mr/hr

Maximum range: \_\_\_\_\_ mr/hr to \_\_\_\_\_ mr/hr

**2. Dose calibrator**

Manufacturer's name: \_\_\_\_\_

Manufacturer's model number: \_\_\_\_\_

Number of instruments available: \_\_\_\_\_

**3. Diagnostic instruments (imaging)**

Type of Instrument	Manufacturer's Name	Model Number
--------------------	---------------------	--------------

**5. Other (counting instruments; airflow measuring instruments)**

## APPENDIX E

### CALIBRATION OF INSTRUMENTS

#### Section 1

- o 1. Survey instruments will be calibrated at least annually and following repair.
- o 2. Survey instruments will be calibrated:
  - a. By the manufacturer
  - b. By the licensee
    - (1) Calibration source, and device if applicable.  
Manufacturer's name: \_\_\_\_\_  
Model number: \_\_\_\_\_  
Activity in millicuries: \_\_\_\_\_  
Accuracy: \_\_\_\_\_  
Traceability to primary standard: \_\_\_\_\_
    - (2) The calibration procedures in Section 2 of Appendix E will be used
    - OR**
    - (3) An equivalent step-by-step procedure, including radiation safety procedures, is attached.
  - c. By an authorized service vendor
    - (1) Name: \_\_\_\_\_
    - (2) Location: \_\_\_\_\_
    - (3) Procedures and sources
      - o Are on file in License No.: \_\_\_\_\_
      - o Are attached.

## CALIBRATION OF DOSE CALIBRATOR

### 1. Sources Used for Linearity Test (Check as appropriate.)

- o First elution from new Mo-99/Tc-99m generator  
OR
- o Other (must be equivalent to the highest activity used. Specify \_\_\_\_\_  
\_\_\_\_\_

### 2. Sources Used for Instrument Accuracy and Constancy Tests

Radionuclide	Calibrated Activity (mCi)	Measured Activity (mCi)	Accuracy
Co-57	_____	_____	_____
Co-60	_____	_____	_____
Cs-137	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

3. o The procedures described in Section 3 of Appendix E will be used for calibration of the dose calibrator.  
OR  
o Equivalent procedures area attached.

## DIAGNOSTIC INSTRUMENTS

Quality assurance, maintenance, and calibration of instruments used for diagnostic purposes shall be performed in accordance with the manufacturer's recommendations.

*Submit a description of your quality assurance, including checks for sensitivity, linearity, spatial distortion, and resolution. See Section 4 for quality assurance procedures for monitoring performance of imaging equipment that has been transported.*

## Section 2

### METHODS FOR CALIBRATION OF (X- AND GAMMA-RAY) SURVEY METERS, INCLUDING PROCEDURES, STANDARDS, AND FREQUENCY.

1. Calibration of survey meters shall be performed with radionuclide sources.
  - a. The sources shall be approximate point sources.

- b. The source activities shall be traceable within five percent accuracy to the U.S. National Institute of Standards and Technology (NIST) calibrations.
- c. The frequency shall be at least annually and after servicing.
- d. Each scale of the instrument shall be calibrated at least at two points such that (1) one point is in each half of the scale and (2) the two points are separated by at least 50 percent of full scale.
- e. The exposure rate measured by the instrument shall differ from the true exposure rate by less than 10 percent of full scale (read appropriate section of the instrument manual to determine how to make necessary adjustments to bring instrument into calibration). Readings greater than  $\pm 10$  percent but within  $\pm 20$  percent will be considered acceptable if a calibration chart or graph is prepared and attached to the instrument

**Note**

Sources of CS-137, RA-226, or Co-60 are appropriate for use in calibrations. The activity of the calibration standard should be sufficient to calibrate the survey meters on all ranges, or at least up to 1 R/hr on the higher range instruments. If there are higher ranges, they should at least be checked for operation and approximately correct response to radiation.

- 2. A reference check source of long half-life, e.g., Cs-137 or Ra-226 shall also be read at the time of the above calibration. The readings shall be taken with the check source placed in specific geometry relative to the detector. A reading of this reference check source should be taken:
  - a. Before each use and also after each survey to ensure that the instrument was operational during the survey.
  - b. After each maintenance and/or batter change.
  - c. At least quarterly.

If any reading with the same geometry is not within  $\pm 20$  percent of the reading measured immediately after calibration, the instrument should be recalibrated (see item A).

- 3. The instrument must be calibrated at lower energies if its response is energy dependent and it is to be used to measure the Xe-133 or Tc-99m energy ranges.

This calibration may be done either:

- a. As in item 1 above with calibrated standards of radionuclides at or near the desired energies, OR

- b. As a relative intercomparison with an energy-independent instrument and uncalibrated radionuclides.
- 4. Records of the above items 1, 2b, 2c, and 3 must be maintained.

5. **Use of Inverse Square Law and Radioactive Decay Law**

- a. A calibrated source will have a calibration certificate giving its output at a given distance measured on a specific date by the manufacturer or NBS.

- (1) The Inverse Square Law may be used with any point source to calculate the exposure rate at other distances.
- (2) The Radioactive Decay Law may be used to calculate and output at other times after the specified date.

b. **Inverse Square Law**

Given a source (S) and exposure rate (R<sub>i</sub>) at a distance (P<sub>i</sub>)

\* - - P<sub>1</sub>

- - - - - P<sub>2</sub>

Exposure rate at P<sub>2</sub>:

$$R_2 = \frac{(P_1)^2}{(P_2)^2} \cdot (R_1)$$

where

S is the point source.

R<sub>1</sub> and R<sub>2</sub> are the same units (mR/hr or R/hr).

P<sub>1</sub> and P<sub>2</sub> are in the same units (centimeters, meters, feet, etc.).

c. **Radioactive Decay Law**

Exposure rate † units of time after specified calibration date.

$$R_{\dagger} = R_0 \times e^{-\frac{0.693}{T_{1/2}} \times \dagger}$$

where

R<sub>0</sub> and R<sub>†</sub> are in the units mR/hr or R/hr.

R<sub>0</sub> is exposure rate on the specified calibration date.

R<sub>†</sub> is exposure rate † units of time later.

$T_{1/2}$  and  $\dagger$  are in the same units (years, months, days, etc.).

$T_{1/2}$  is radionuclide half-life.

$\dagger$  is number of units of time elapse between calibration and present time

- d. **Example:** Source output is given by calibration certificate as 100 mR/hr at 1 foot on March 10, 1975. Radionuclide half-life is 5.27 years.

**Question:** What is the output at 3 feet on March 10, 1977 (2.0 years)?

- (1) Output at 1 foot, 2.0 years after calibration date:

$$\begin{aligned} R &= 100 \text{ mR/hr} \times e^{-\frac{(0.693 \times 2.0)}{5.3}} \\ &= 100 \times 0.77 = 77 \text{ mR/hr at 1 foot on March 10, 1977} \end{aligned}$$

- (2) Output at 3 feet, 2.0 years after calibration date:

$$\begin{aligned} R_3 &= \frac{(1 \text{ foot})^2}{(3 \text{ foot})^2} \times 77 \text{ mR/hr} \\ &= T/9 \times 77 = 8.6 \text{ mR/hr at 3 feet, 2.0 years after calibration} \end{aligned}$$

### Section 3

#### METHODS FOR CALIBRATION OF DOSE CALIBRATOR

All photon-emitting radiopharmaceuticals must be assayed for activity to an accuracy of ten percent. The most common instrument for accomplishing this is an ionization-type dose calibrator. The instrument must be checked for accurate operation at the time of installation and periodically thereafter.

Test for the following:

1. Constancy (daily or before each use).
2. Instrument linearity (at installation and quarterly thereafter).
3. Geometrical variation (at installation).
4. Instrument accuracy (at installation and annually thereafter).

After repair or adjustment of the dose calibrator, repeat all the appropriate tests listed above (dependent upon the nature of repairs).

## 1. Test for Instrument Constancy

Assay two reference sources such as Cs-137 and Co-57 using a reproducible geometry before each daily use of the instrument (3-5 mCi of Co-57, minimum of 50 microcuries for Cs-137 or Ra 226).

- a. Assay each reference source using the appropriate setting (i.e., Cs-137 setting for Cs-137).
- b. Measure background level at same time instrument setting, and subtract or confirm the proper operation of the automatic background subtract circuit if used.
- c. Calculate net activity of each source subtracting out background count.
- d. The above check should be repeated during the day whenever sample readings are not within ten percent of the anticipated assay.
- e. For each source, either plot on semi-log paper or log in a book, the net activity versus the day of the year, and the attendant background activity.
- f. Indicate the predicted activity of each source based on decay calculations and the  $\pm$  percent limits on the graph or log book.
- g. Using one of the sources, repeat the above procedure for all commonly used radioisotope settings. Plot or log the results.
- h. Variations greater than  $\pm$  percent from the predicted activity indicate the need for instrument repair or adjustment.
- i. Investigate higher than normal background levels to determine their origin to eliminate them if possible by decontamination, relocation, etc.

Investigate the instrument on a quarterly basis to ascertain that the measurement chamber liner is in place and that the instrument zero is properly set (see manufacturer's instructions).

## 2. Test of Instrument Linearity

The linearity of a dose calibrator should be ascertained over the entire range of activities employed. This test will utilize a vial or syringe of Tc-99m whose activity is at least equivalent to the maximum activity normally assayed in a prepared radiopharmaceutical kit or in a radiopharmaceutical therapy, whichever is largest.

### Decay Method

- a. Assay the Tc-99m vial or syringe in the dose calibrator and subtract background level to obtain net activity in millicuries. Record the date, time, and net activity.
- b. Repeat step a. at time intervals of 6, 24, 30, and 48 hours after the initial assay.
- c. Using the 30-hour activity measurement as a starting point, calculate the predicted activities at 0, 6, 24, and 48 hours using the following table:

Assay Time (Hour)	Correction Factor
0	32.000
6	16.000
24	2.000
30	1.000
48	0.125

**Example:** If the net activity measured at 30 hours was 15.625 mCi, the predicted activity for 6 and 48 hours would be  $15.625 \text{ mCi} \times 16 = 250 \text{ mCi}$  and  $15.625 \text{ mCi} \times 0.125 = 1.95 \text{ mCi}$ , respectively.

- d. Plot or log the measured net activity for each time interval versus the predicted activity. The measured activity should be within  $\pm$  percent of the predicted activity if the instrument is linear and functioning properly. Errors greater than  $\pm$  percent indicate the need for repair or adjustment of the instrument.
- e. If instrument linearity cannot be corrected, it will be necessary in routine assays to either assay an aliquot of the eluate that can be accurately measured or to use the graph constructed in step 4 to relate measured activities to true activities.
- f. Place a sticker on the dose calibrator, indicating when the next test is due.

### Shield Method

Linearity may also be checked using a set of “sleeves” of various thickness’ if the sleeves are calibrated to equivalent decay times. Submit your procedures if you plan to use this method.

Regardless of method used, if instrument linearity cannot be corrected, it will be necessary in routine assays to either assay an aliquot of the eluate that can be accurately measured or to use the constructed graph to relate measured activities to true activities.

### 3. Test for Geometrical Variation

There may be significant geometrical variation in activity measured as a function of sample volume or configuration, depending on the volume and size of the ionization chamber used in the dose calibrator. The extent of geometrical



variation should be ascertained for commonly used radionuclides and appropriate correction factors computed if variations are significant, i.e., greater than  $\pm 2$  percent. (Even though correction factors may be provided by the manufacturer, the accuracy of these should be checked.)

To measure variation with a volume of liquid, a 30 ml vial containing 2 mCi of Tc-99m or other appropriate radionuclide in a volume of 1 ml will be used.

- a. Assay vial at the appropriate instrument setting and subtract background level to obtain net activity.
- b. Increase the volume of liquid in the vial in steps to 2, 38, 48, 10, 20, and 25 ml by adding the appropriate amount of water or saline. After each addition, gently shake vial to mix contents and assay as in step 1. The entire process must be completed within ten minutes.
- c. Select one volume as a standard (such as the volume of reference standard used in performing the test for instrument accuracy), and calculate the ratio of measured activities for each volume to the reference volume activity. This represents the volume correction factor (CF).

**Example:** If activities of 2.04, 2.02, and 2.00 mCi are measured for 4, 8, and 10 ml volumes and 10 ml is the reference volume selected:

$$4 \text{ ml Volume CF} = \frac{2.00}{2.04} = 0.98$$

- d. Plot the correction factors against the volume in linear graph paper. Use this graph to select the proper volume correction factors for routine assay of that radionuclide.
- e. The true activity of a sample is calculated as follows:

$$\text{True Activity} = \text{Measured Activity} \times \text{Correction Factor}$$

where the correction factor used is for the same volume and geometrical configuration as the sample measured.

- f. For licensees using unit doses only, the geometrical dependence may be verified by using a syringe normally used for injections:
  - (1) Draw out 0.5 ml of the radioactive solution (1 to 10 mCi in 2 ml) and assay it. Record the volume and millicuries.
  - (2) Increase the volume of liquid in the syringe in increments of 0.5 ml using saline or tap water until a 2 ml volume for a 3 ml syringe (adjust as appropriate for other syringe sizes) is attained. Assay and record the volume and millicuries each time the volume is increased.

- (3) Repeat steps c through e above.
- g. It should be noted that differences of 200 percent in dose calibrator readings between glass and plastic syringes have been observed for lower energy radionuclides such as I-125. Hence, adequate correction factors must be established for this type of syringe.

#### 4. **Test of Instrument Accuracy**

Check the accuracy of the dose calibrator for several radionuclides such as Cs-137, Co-57, and Co-60 using appropriate reference standards whose activity is traceable to NIST. The activity levels of the reference sources used should approximate those levels normally encountered ( $> 50$  uCi), giving adequate attention to source configuration. The lower energy reference standards (Tc-99m, Xe-133, I-125) must be in vials with the same thickness of glass as the actual samples to be measured for best accuracy.

- a. Assay the reference standard in the dose calibrator at the appropriate setting and subtract the background level to obtain the net activity.
- b. Repeat step a. for a total of three determinations, and average results.
- c. The average activity determined in step b. must agree with the certified activity of the reference source within  $\pm$  percent after decay corrections.
- d. Repeat the above steps for other commonly-used radionuclides for which adequate reference standards are available.
- e. Keep a log of these calibration checks.
- f. Calibration checks that do not agree with  $\pm 5$  percent indicate that the instrument needs to be repaired or adjusted. If this is not possible, a calibration factor must be calculated for use during routine assays of radionuclides.
- g. At the same time the instrument is being initially calibrated with the NIST-traceable standards, place a long-lived source in the calibrator, set the instrument, in turn, at the various radionuclide settings used (Cs-137, I-131, Tc-99m, I-125, etc.) and record the readings. These values may later be used to check instrument constancy at each setting (after correcting for decay of the long-lived source) without requiring more NIST-traceable standards. Keep a log of these initial and subsequent readings.
- h. Place a sticker on the dose calibrator, indicating when the next test is due.

## Section 4

### MODEL PROCEDURE FOR MONITORING PERFORMANCE OF IMAGING EQUIPMENT\*

1. Perform the following checks daily at each location of use before administering radioactive material:
  - a. Peak each camera according to the manufacturer's instructions.
  - b. With a frequently used collimator in place, image a flood field of either Tc-99m or Co-57. Accumulate at least 1,000,000 counts for small-field-of-view cameras and 3,000,000 counts for large field of view cameras. Process the image as if it were an image of a patient.
2. Perform the following checks weekly:
  - a. With the same frequently used collimator in place, image a parallel-line-equal-space (PLES), parallel-line-unequal-space, orthogonal-hole (OH), or resolution-quadrant phantom with the flood field as a source to test for resolution. Ensure that the phantom used is appropriate for the resolving power of the camera.
  - b. If a PLES is used, rotate it 90 degrees so that the camera is tested for both vertical and horizontal geometry linearity.
  - c. If a resolution-quadrant phantom is used, rotate it so that each quadrant is imaged in each quadrant of the crystal. This procedure will check both resolution and horizontal/vertical geometric linearity in each quadrant of the crystal.
  - d. Process the images as if they are images of a patient. Mark them clearly to indicate image orientation, source activity, and date.
  - e. Sensitivity measurements may be made with a measured source of Tc-99m (intrinsic) or with a Co-57 flood source (extrinsic) which has been corrected for decay. With the camera uniformity correction disabled, acquire a flood. Record time of acquisition, source activity, and total flood count. Calculate sensitivity as follows: total count divided by time of acquisition (seconds) divided by source activity (uCi) equals—cps/uCi.
  - f. Retain the images and measurements for three years.

\*For SPECT studies, see item 11.c.

3. Perform the following safety checks quarterly and after each repair:
  - a. Check the motion interlocks by activating the emergency-off switches on the camera. With the camera in motion, activation of the emergency-off switch should stop the motion. If this might jeopardize imaging components in the system, perform only the checks described in paragraph 3b.
  - b. Check the motion switches. Put the camera in motion and first release just the direction switch to stop the motion. Then put the camera back in motion and release just the dead-man switch. Test all motion switches and all directions in this manner. Release of either motion switch or the dead-man switch alone should disable the camera motion. If this is not the case, repair the camera before clinical use.
  - c. Set the equipment in the same manner each time checks are run. Make a record of all these checks. Keep a separate file or ring binder for each camera. Retain the record for three years.

## **APPENDIX F**

### **PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIALS**

1. The Radiation Safety Officer (RSO) or a sole designee must authorize each order for radioactive materials and ensure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded.
2. The RSO will establish and maintain a system for ordering and receiving radioactive material. The system must contain the following information:
  - a. For routinely used materials
    - (1) Written records that identify the authorized user or department, isotope, chemical form, activity, and supplier will be made.
    - (2) The above records will be checked to confirm that material received was ordered through proper channels.
  - b. For occasionally used material (e.g., therapeutic dosages)
    - (1) The authorized user who will perform the procedure will make a written request that indicates the isotope, compound, activity, and supplier.
    - (2) The person who receives the material will check the physician's written request to confirm that the material received is what was ordered.
3. During normal working hours, carriers must be instructed to deliver radioactive packages directly to a specified area (e.g., the RSO, the Nuclear Medicine or Radiation Oncology department).
4. During off-duty hours, specifically designated personnel, i.e., security or emergency room personnel, must accept delivery of radioactive packages in accordance with the procedures outlined in the sample memorandum below.

## SAMPLE MEMORANDUM

MEMO TO: Security or Emergency Room Personnel

FROM: John Dow, Administrator

SUBJECT: Receipt of Packages Containing Radioactive Material

Any packages containing radioactive material that arrive between 4:30 p.m. and 7:00 a.m. or on weekends shall be signed for by the security guard on duty and taken immediately to the Nuclear Medicine Department. Unlock the door, place the package on top of the counter immediately to the right of the door, and relock the door.

If the package is wet or appears to be damaged, *immediately* contact the hospital Radiation Safety Officer. Ask the carrier to remain at the hospital until it can be determined that neither they or the delivery vehicle is contaminated.

**Name**

**Home Telephone**

RADIATION SAFETY OFFICER: \_\_\_\_\_

CHIEF OF NUCLEAR MEDICINE: \_\_\_\_\_

CHIEF NUCLEAR MEDICINE TECHNOLOGIST: \_\_\_\_\_

## **APPENDIX G**

### **PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL**

1. Put on gloves.
2. Visually inspect packages for any sign of damage (e.g., wetness, crushed). If damage is noted, stop procedure and notify Radiation Safety Officer.
3. Measure exposure rate at one meter from package surface and record. If > 10 mR/hr or twice the Transport Index noted on the package or paper, stop procedure and notify Radiation Safety Officer.
4. Measure surface exposure rate and record. If > 200 mR/hr, stop procedure and notify Radiation Safety Officer.
5. Open the outer package (following manufacturer's directions, if supplied) and remove package slip. Open inner package to verify contents (compare requisition, packing slip, and label on bottle). Check integrity of final source container (inspecting for breakage of seals or vials, loss of liquid, discoloration of packaging material). In case of irregular findings, notify the Radiation Safety Officer.
6. If leakage or contamination is suspected, determine the extent of contamination (to enable initiation of safety precautions commensurate with the level of contamination) by wiping the external surface of the final source container with a cotton swab held with forceps; assay and record.
7. Check to ensure that shipment does not exceed possession limit.
8. Monitor the packing material and packages for contamination before discarding.
  - a. If contaminated (above twice natural background rate), treat as radioactive waste.
  - b. If not contaminated, obliterate radiation labels before discarding in regular trash.

In all wipe sample surveys, remove wipe samples to a low-background area and check with a thin window ( $< 7 \text{ mg/cm}^2$  thickness preferred) GM survey meter or a scintillation probe or liquid scintillation counter, if appropriate. Precautions should be taken to prevent the spread of contamination.

See Exhibit 3 for a sample record form.

## APPENDIX H

### RECORDS OF RADIOACTIVE MATERIALS USE

Several suppliers include pressure-sensitive stickers that have much of the information required by regulations. Licensees may use these stickers in their log books, and only supplement them where the required information is not provided. Licensees do not have to replicate entries. For example, when a multidose vial is prepared for one day, the licensee does not have to record the date each time a dose is withdrawn from it: when 30 Ir-192 seeds (each 0.5 mCi) are taken out, it is not necessary to list each seed individually.

#### Records of Dosage Use

1. **Unit Dosage** (A patient's prescription that requires no further processing before administration)

The log must indicate the supplier, radionuclide and chemical form or trade name, date of receipt, and lot number. If used, time of administration, measured activity (mCi), patient name, and ID number; if discarded, the method of disposal.

See Exhibit 4 for sample record form.

2. **Multidose Vial Use**

In addition to the information in section 1 above, also maintain records showing date and time of initial activity assay in millicuries and volume, and kit manufacturer. If administered, the date and time dosage was withdrawn, prescribed dosage, measured activity (mCi) and concentration (cc/mCi), and total volume (ml).

See Exhibit 5 for sample record form.

3. **Measuring and Recording Molybdenum Concentration**

A licensee who uses Mo-99/Tc-99m generators to prepare radiopharmaceuticals must test each elution or extraction for its molybdenum concentration (need not be done when using prepared radiopharmaceuticals from a distributor). This measurement is usually made with a dose calibrator.

The model procedure is based on the use of a "molybdenum breakthrough pig". Your dose calibrator manufacturer will usually supply as an option a molybdenum breakthrough pig made of lead. The pig is usually thick enough to shield all the technetium photons but only a fraction of the molybdenum photons. The manufacturer will specify the Mo-99 correction factor to convert from measured Mo-99 to total Mo-99.



The following model procedure may be used to measure the molybdenum concentration in a Mo-99/Tc-99m generator elution:

For each generator elution, make a record of the:

- a. Date the generator was received.
- b. Date and time of elution.
- c. Measured Mo-99 activity in microcuries.
- d. Product of the measured Mo-99 activity and the correction factor noted by the molybdenum breakthrough pig manufacturer.
- e. Measured Tc-99m activity in millicuries.
- f. Ratio of the total Mo-99 microcuries per millicuries of Tc-99m and check that the ratio is less than 0.07 microcurie of Mo-99 per millicurie of Tc-99m. (If it is not, stop and notify the Radiation Safety Officer.) (The 0.07 action levels allows for the quicker decay of the Tc through the day of use.) It is assumed that the material will be used within six hours, at which time the ratio could only have doubled.
- g. Initials of the person who made the record.

See Exhibit 6 for sample record form.

#### 4. **Keeping an Inventory of Implant Sources**

You may use the following model procedure to keep an inventory and use record for implant sources.

- a. Use a locking safe to store all implant sources.
- b. Make a list of names of those individuals you allow to handle implant sources and have them initial beside their names.
- c. For long-lived sources, draw a map of the storage drawer and indicate the activity of the source at each storage point. For short-lived sources that you stored in the manufacturer's shipping container, indicate the area in the safe where you put the container. Also, be sure to add the sources to the inventory log.
- d. Post the map and a list of individuals whom you permit to handle the sources in the storage area or on the inventory log.
- e. Each time you remove a source, make a record of the number and activity of sources removed, the room number of use or patient's name, the time and date they are removed from storage, and initial the record.

- f. Each time you return sources to storage, immediately count them to ensure that every source removed has been returned. Then make a record of the number and activity of sources returned, the room number of use or patient's name, the time and date they were returned to storage, and initial the record.
- g. If you ever perceive a discrepancy between the record and the number of sources in use and in storage, notify the Radiation Safety Officer immediately.

See Exhibit 7 for a sample form you may want to use.

## **APPENDIX I**

### **GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL**

1. Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.
2. Wear disposal gloves at all times while handling radioactive materials.
3. Monitor hands and clothing for contamination after each procedure or before leaving the area.
4. Use syringe shields for preparation of patient doses and administration to patients except in circumstances such as pediatric cases when their use would compromise the patient's well being.
5. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.
6. Do not store food, drink, or personal items in areas where radioactive material is stored or used.
7. Wear personnel monitoring devices (film badge or TLD) at all times while in areas where radioactive materials are used or stored. These devices should be worn at chest level (or at waist level when device is not shielded by work benches, etc.).
8. Wear TLD finger badges during elution of generator and preparation, assay, and injection of radiopharmaceuticals.
9. Dispose of radioactive waste only in specifically-designated receptacles.
10. Never pipette by mouth.
11. Survey generator, kit preparation, and injection areas for contamination after each procedure or at the end of the day. Decontaminate if necessary.
12. Confine radioactive solutions in covered containers plainly identified and labeled with the name of the compound, radionuclide, date, activity, and radiation level, if applicable.
13. Always label syringes and unit doses to indicate the radiopharmaceutical, activity (mCi), type of study, and name of the patient.
14. Assay each patient dose in the dose calibrator to administration. Do not use any doses that differ from the prescribed dose by more than ten percent.
15. Do not use radiopharmaceutical containing more than 0.15 microcurie of Mo-99 per 1.0 millicurie of Tc-99m.
16. Always transport radioactive material in shielded containers.

## APPENDIX J

### AREA SURVEY PROCEDURES

1. All elution, preparation, and injection areas will be surveyed daily with a low-range survey meter (see item 10) and decontaminated if necessary.
2. Laboratory areas where only small quantities of radioactive material are used (less than 200 uCi) will be surveyed monthly.
3. All other laboratory areas will be surveyed weekly.
4. The weekly and monthly survey will consist of:
  - a. A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mR/hr.
  - b. A series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect 2,000 dpm per 100 cm<sup>2</sup> for the contaminant (200 dpm/100 cm<sup>2</sup> for iodine) involved.
5. A permanent record will be kept of all survey results, including negative results. The record will include:
  - a. Location, date, and type of equipment used.
  - b. Name of person conducting the survey.
  - c. Drawing of area surveyed, identifying relevant features such as active storage areas, active waste areas, etc.
  - d. Measured exposure rates, keyed to location on the drawing (point out rates that require corrective action).
  - e. Detected contamination levels, keyed to locations on drawing.
  - f. Corrective action taken in the case of contamination or excessive exposure rates, reduced contamination levels or exposure rates after corrective action, and any appropriate comments.
6. An area will be decontaminated and resurveyed if the contamination level exceeds 2,000 dpm/100 cm<sup>2</sup> for iodine.

#### NOTE:

For daily surveys where no abnormal exposures are found, only the date and the identification of the person performing the survey need to be recorded.

See Exhibit 8 for sample record form.

**APPENDIX K**  
**EMERGENCY PROCEDURES**

**Minor Spills** ( $\leq 0.1$  mCi Iodine, 1.0 mCi other radionuclides)

1. NOTIFY: Notify persons in the area that a spill has occurred.
2. PREVENT THE SPREAD: Cover the spill with absorbent paper.
3. CLEAN UP: Use disposable gloves and remote handling tongs. Carefully fold the absorbent paper and pad. Insert into a plastic bag and dispose of in the radioactive waste container. Also insert into the plastic bag all other contaminated materials such as disposable gloves.
4. SURVEY: With a thin window GM or scintillation survey meter, check the area around the spill, hands, and clothing for contamination.
5. REPORT: Report incident to the Radiation Safety Officer (RSO).

**Major Spills**

1. CLEAR THE AREA: Notify all persons not involved in the spill to vacate the room.
2. PREVENT THE SPREAD: Cover the spill with absorbent pads, but do not attempt to clean it up. Confine the movement of all personnel potentially contaminated to prevent the spread.
3. SHIELD THE SOURCE: If possible, the spill should be shielded, but only if it can be done without further contamination or without significantly increasing your radiation exposure.
4. CLOSE THE ROOM: Leave the room and lock the door(s) to prevent entry.
5. CALL FOR HELP: Notify the RSO immediately.
6. PERSONNEL DECONTAMINATION: Contaminated clothing should be removed and stored for further evaluation by the RSO. If the spill is on the skin, flush thoroughly and then wash with mild soap and lukewarm water.
7. The RSO will supervise the cleanup of the spill and will complete the radioactive spill and decontamination report.

**Name**

**Telephone Number**

Radiation Safety Officer: \_\_\_\_\_

Chief Nuclear Medicine  
Technologist: \_\_\_\_\_

See Exhibit 9 for sample form.

**APPENDIX L**  
**WASTE DISPOSAL**

1. Liquid waste will be disposed of (check as appropriate):
  - o By confirmed waste disposal service (see also item 4 below).
  - o In the sanitary sewer system in accordance with Section 30287 (see Exhibit 10).
  - o Other (specify): \_\_\_\_\_  
\_\_\_\_\_
2. Mo-99/Tc-99m generators will be (check as appropriate):
  - o Returned to the manufacturer for disposal.
  - o Held for decay until radiation levels, as measured with a low-level survey meter and with all shielding removed, have reached levels not statistically significant as compared with background levels.\* All radiation labels will be removed or obliterated and the generators disposed of as normal trash. (Note: This method of disposal may not be practical for generators containing long-lived radioactive contaminants.)
  - o Disposed of by commercial waste disposal service (see also item 4 below).
  - o Other (specify): \_\_\_\_\_  
\_\_\_\_\_
3. Other solid waste will be (check as appropriate):
  - o Held for decay until radiation levels, as measured with a low-level survey meter and with all shielding removed, have reached levels not statistically significant as compared with background levels.\* All radiation labels will be removed or obliterated and the waste will be disposed of in normal trash. (Note: This method is not permissible for low-energy beta-emitters, e.g., tritium, Carbon 14, and Sulfur 35.)
  - o Other (specify): \_\_\_\_\_  
\_\_\_\_\_

\*The radioactive materials must have decayed through ten half-lives and with a thin window GM (< 7 mg/cm<sup>2</sup> thickness) or scintillation (if appropriate) survey meter, the exposure rate is normally taken as twice the natural background rate.

4.     o     The commercial waste disposal service used will be:

Name: \_\_\_\_\_

City/State: \_\_\_\_\_

NRC/Agreement State License Number: \_\_\_\_\_

OR

- o     Any commercial disposal service authorized by a California (NRC/Agreement State) license to perform such service. Documented authorization will be maintained for inspection.

## **APPENDIX M**

### **THERAPEUTIC USE OF RADIOPHARMACEUTICALS**

1. All patients treated with Iodine-131 shall be placed in a private room with a toilet. The room and toilet areas most likely to be contaminated will be covered with protective material as appropriate, to the amounts of expected contamination. Particular attention should be given to objects likely to be touched by the patient, e.g., telephones, doorknobs, and other items that would be difficult to decontaminate.
2. The patient's room will be as far away from the nursing station and heavy traffic hallways as is consistent with good medical care.
3. The patient's room will be properly posted in accordance with 10 CFR Part 20.1902.
4. Surveys of the patient's room and surrounding areas will be conducted as soon as practicable after administration of the treatment dosage. Exposure rates will be measured at the patient's bedside, at one meter from the bed, and at the entrance to the room and in adjoining rooms above and below when appropriate. The Radiation Safety Officer or designee designate stay times at these positions and will post these times on the patient's chart and on the room door. The results of daily surveys will be used to recalculate permitted times, which will be posted on the patient's chart and door.
5. "Brief" the nurses on radiation safety precautions, and "supplement" this by completing the form "Nursing Instructions for Patients Treated with Phosphorus-32 and Iodine-131" immediately after administration of the treatment dosage. A copy will be posted on the patient's chart.
6. Radiation levels in unrestricted areas will be maintained less than limits specified in Part 20.1301.
7. Tissue, surgical dressings, and other similar waste items will be placed in a specifically designated container. The material in the container will be considered contaminated and held for decay prior to disposal as normal waste.
8. All linens and other nondisposable items used for these patients will be held in plastic bags and will be checked for contamination by the Radiation Safety Officer or designee prior to release. Items may be returned for normal use or held for decay or decontamination, as appropriate.
9. Urine and vomitus from Iodine-131 therapy patients should be flushed down the toilet whenever possible.



10. Before a therapy patient's room is reassigned to another patient, the room will be surveyed for contamination and decontaminated if necessary, and all radioactive waste and waste containers will be removed. The room will be considered clean if contamination is less than 200 dpm/100 cm<sup>2</sup>.
11. Prior to administration, brief the patient on radiation safety procedures, visitor control, urine collection, radioactive waste, and other items as applicable.
12. Only persons needed for medical, safety, or training purposes will be present during the administration.
13. Mark a visitors' "safe line" on the floor with a tape as far from the patient as possible.
14. Supply the nurses with film badges or TLD, as required by Part 20.1502. The dosimetry device must be worn only by the nurse to whom it is issued; it must not be exchanged between nurses.
15. A patient containing I-131 may be released without restrictions if the exposure rate at one meter from the patient is 2 mR/hr or less, or if the activity is 8 mCi or less. Higher levels of activity or exposure rates are permitted with restrictions. Consult NCRP Report No. 37 for release of patients containing other radionuclides.

If the exposure rate at one meter is between 2 mR/hr and 18 mR/hr and or if the activity in the patient is between 8 and 80 mCi, the patient shall be given both oral and written radiation/contamination precautionary instructions prior to discharge. Certain restrictions must be imposed on the release of the patient. Consult NCRP Report No. 37 for the detail pertaining to the age of persons in the household.

(See Exhibit 11 for Nursing Instructions to be posted on the patient's chart; Exhibit 12 is an acceptable radiation safety instruction for discharged patients.

**16. Radiation Safety Precautions for Patient Care Staff**

- a. Nurses and other patient care staff should spend only the minimum amount of time near the patient for ordinary nursing care. Special restrictions may be noted on the precaution sheet on the patient's chart. Nurses must read these restrictions before administering to the patient. Call the Radiation Safety Officer with any questions about the care of these patients.
- b. Visitors will be limited to those 18 years of age or over unless other instructions are noted on the precaution sheet on the patient's chart.
- c. Patients must remain in bed while visitors are in the room and visitors should remain at least three feet from the patient, or behind the established visitor line.
- d. Patients containing radioactive materials are to be confined to their rooms except for special medical or nursing purposes approved by the Radiation Safety Officer.

- e. No nurse, visitor, or attendant who is pregnant should be permitted in the room of a patient who has received a therapeutic amount of radioactivity until the patient no longer presents a radiation hazard. Female visitors should be asked whether they are pregnant.
- f. Attending personnel should wear rubber or disposable plastic gloves when handling urinals, bedpans, emesis basins, or other containers having any material obtained from the body of the patient. Wash gloves before removing and then wash hands. The gloves should be left in the patient's room in the designated waste container. These gloves need not be sterile or surgical in type.
- g. Disposable items should be used in the care of these patients, whenever possible. These items should be placed in the designated waste container. Contact with the Radiation Safety Officer or their designee for proper disposal of the contents of the designated waste container.
- h. All clothes and bed linens used by the patient should be placed in the laundry bag provided and should be left in the patient's room to be checked by the Radiation Safety Officer or their designee.
- i. All nondisposable items should be placed in a plastic bag and should be left in the patient's room to be checked by the Radiation Safety Officer or their designee.
- j. Surgical dressings should be changed only as directed by the physician. Such dressings shall not be discarded but should be collected in plastic bags and turned over to the Radiation Safety Officer or their designee. Handle these dressings only with tongs or tweezers. Wear disposable gloves.
- k. For Iodine 131 patients:
  - (1) The patient should use the toilet facilities available in the room; but whenever it is desirable to collect the urine for assay, it will be collected in special containers provided by the Radiation Safety Officer or their designee. The patient should be encouraged to collect their own urine in the container. If the patient is bedridden, a separate urinal or bedpan should be provided. The urinal or bedpan should be flushed several times with hot soapy water after use.
  - (2) If the nurse helps collect the excreta, disposable gloves should be worn. Afterwards, hands should be washed with the gloves on and again after the gloves are removed. The gloves should be placed in the designated waste container for disposal by the Radiation Safety Officer or their designee.
  - (3) Vomiting within 24 hours after oral administration, urinary incontinence, or excessive sweating within the first 48 hours may result in contamination of linen and floor. In any such situations or if radioactive urine and/or feces is spilled during collection, call the Radiation Safety Officer or their designee, Ext. \_\_\_\_\_. Meanwhile, handle all contaminated material with disposable gloves and avoid spreading contamination.

- (4) Vomitus may be flushed down the toilet. Feces need not be routinely saved, unless ordered on the chart. The same toilet should be used by the patient at all times, and it should be well flushed (three times).
- l. Utmost precautions must be taken to see that no urine or vomitus is spilled on the floor or the bed. If any part of the patient's room is suspected to be contaminated, notify the Radiation Safety Officer or their designee.
- m. If a nurse, attendant, or anyone else knows or suspects that their skin or clothing, including shoes, is contaminated, notify the Radiation Safety Officer or their designee immediately. This person should remain in an area adjacent to the patient's room and should not walk about the hospital. If the hands become contaminated, wash them immediately with soap and water.
- n. If a therapy patient should need emergency surgery or should die, notify the Radiation Safety Officer or the Nuclear Medicine Department immediately. The Radiation Safety Officer shall initiate radiation safety precautions (e.g., as outlined in Section 5 of the NCRP Report No. 37).
- o. When the patient is discharged, call the Radiation Safety Officer or their designee or the Nuclear Medicine Department and request that the room be surveyed for contamination before remaking the room.

## APPENDIX N

### THERAPEUTIC USE OF SEALED SOURCES

1. All patients treated with brachytherapy sources will be placed in a private room with toilet, and the room will be as far away from the nursing station and heavy traffic hallways as is consistent with good medical care.
2. The patient's room will be properly posted in accordance with Section 30278.
3. "Brief" the patient on safety procedures for confinement to bed, visitor control, and other items consistent with good medical care.
4. Surveys of the patient's room and surrounding areas will be conducted as soon as practicable after sources are implanted. Exposure rate measurements will be taken at the patient's bedside, at one meter from the bed, and at the entrance to the room. The Radiation Safety Officer or their designee will then determine how long a person may remain at these positions and will post these times and the exposure rate at one meter from the bed on the patient's chart.
5. "Brief" the nurses on radiation safety procedures, and "supplement" immediately after sources are implanted by completing the form "Nursing Instructions for Patients Treated with Brachytherapy Sources" and placing it on the patient's chart. (See Exhibit 13 for typical Nursing Instructions to be posted on the patient's chart.)
6. Only those needed for medical, safety, or training should be present during the implant procedure.
7. Radiation levels in unrestricted areas shall be maintained less than the limits specified in Section 30268.
8. Nurses caring for brachytherapy patients shall be assigned dosimetry devices. Finger badges will also be assigned to nurses who must provide extended personal care to the patient.
9. At the conclusion of treatment, a survey shall be performed to ensure that all sources have been removed from the patient and that no sources remain in the patient's room or any other area occupied by the patient. At the same time, all radiation signs will be removed, and all film and TLD badges assigned to nurses will be collected.
10. Patients with permanent implants may be released from the hospital if the exposure rate from the patient is less than 2 mR/hr at one meter.

If the exposure rate is between 2 mR/hr and 5 mR/hr at one meter, the patient shall be given both oral and written radiation safety instructions prior to discharge.

Above 5 mR/hr at one meter, a patient shall not be discharged from the hospital.

## 11. Instructions to Nurses

- a. Special restrictions may be noted on the precaution sheet on the patient's chart. Nurses should read these instructions before administering to the patient. Call the Radiation Safety Officer or their designee with any questions about the care of these patients in regard to radiation safety precautions.
- b. Nurses should spend only the minimum time necessary near a patient for routine nursing care.
- c. When a nurse receives an assignment to a therapy patient, a dosimetry device (e.g., film or TLD badge) should be obtained immediately from the Radiation Safety Officer or their designee. The device shall be worn only by the nurse to whom it is issued and shall not be exchanged between nurses.
- d. Pregnant nurse should not be assigned to the personal care of these patients.
- e. Never touch needles, capsules, or containers holding brachytherapy sources. If a source becomes dislodged, use long forceps and put it in the corner of the room or in the shielded container provided; contact Radiation Therapy, the Radiation Safety Officer, or the Nuclear Medicine Department at once.
- f. Bed baths given by the nurse should be omitted while the sources are in place.
- g. Perineal care is not given during gynecologic treatment; the perineal pad may be changed when necessary unless orders to the contrary have been written.
- h. Surgical dressings and bandages used to cover the area of needle insertion may be changed only by the attending physician or radiologist, and SHALL NOT BE DISCARDED until directed by the radiologist. Dressings should be kept in a basin until checked by the Radiation Safety Officer or their designee.

Special orders will be written for oral hygiene for patients with oral implants.

- i. No special precautions are needed for sputum, urine, vomitus, stools, dishes, instruments, or utensils unless specifically ordered, but these items should be saved for a check with a radiation survey meter to ensure that no sources have been inadvertently displaced into these items.
- j. All bed linens shall be checked with a radiation survey meter before being removed from the patient's room to ensure that no dislodged sources are inadvertently removed.
- k. These patients must stay in bed unless orders to the contrary are written. In any event, patients shall remain in their assigned rooms during the treatment period.
- l. Visitors will be limited to those 18 years of age or over, unless other instructions are noted on the precaution sheet on the patient's chart.
- m. Visitors should sit at least three feet (or one meter) from the patient and should remain no longer than the time specified on the form posted on the patient's door and on their chart.

- n. No nurse, visitor, or attendant who is pregnant should be permitted in the room of a patient when brachytherapy sources are implanted in the patient. Female visitors should be asked whether they are pregnant.

o. **Emergency Procedures**

- (1) If an implanted source becomes loose or separated from the patient, or
- (2) If the patient dies, or
- (3) If the patient requires emergency surgery, *immediately* call:

Name: \_\_\_\_\_

Telephone Number (days): \_\_\_\_\_ (nights) \_\_\_\_\_

- p. At the conclusion of treatment, call the Radiation Safety Officer to (1) survey the patient and room and (2) count the radiation sources to be sure that all temporary implants have been removed prior to discharging the patient.

## APPENDIX O

### PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES AND AEROSOLS (e.g., XENON 133)

The following information should be submitted in support of request to use Xenon 133:

#### 1. Quantities to be Used

##### a. Patient Information

- (1) Number of studies expected per week.
- (2) Average activity per patient.

- b. State the desired possession limit. This should be sufficient to provide for shipments whose calibration dates are several days after receipt.

#### 2. Use and Storage Areas

- a. Describe the area(s) in which you plan to use and store Xenon 133. Include a diagram indicating the availability of shielding materials and the proximity to unrestricted areas.
- b. Describe the ventilation in all areas where Xenon 133 is used and stored. The locations of supply and exhaust vents, the measured airflow rate for each vent, and the fraction of air that is recirculated by the system should be indicated. Storage of multidosage quantities shall be in a fume hood.
- c. All areas where xenon is used shall be under negative pressure. State how you will ensure that all airflow rates are maintained as specified in this application.
- d. The ventilation flow rates (including fume hood) shall be tested at intervals not to exceed 12 months and following any repairs that affect the ventilation system.

#### 3. Procedures for Routine Use

- a. Describe the procedures to be followed for routine use of Xenon 133, giving particular attention to radiological safety factors.
- b. If you plan to use a special apparatus for administration and collection of Xenon 133, specify the manufacturer's name and model number and include a description of its design characteristics. (Inclusion of a brochure would be helpful.)
- c. Describe any special procedures that you plan to employ to reduce leakage, e.g., use of nose clamps or special enclosures.

#### 4. Emergency Procedures

Describe the emergency procedures to be used in case of an accidental release of Xenon 133. This should include such considerations as temporary evacuation of the area or increasing the ventilation of the area.

## 5. Air Concentrations of Xenon 133 in Restricted Areas

No licensee shall permit any individual in a restricted area to inhale a quantity of radioactive material in any period of one calendar quarter greater than the quantity that would result from inhalation for 40 hours per week for 13 weeks at uniform concentrations of radioactive material of  $1 \times 10^{-5}$  uCi/ml.

You may evaluate your situation by making actual measurements of Xenon 133 concentrations or by means of calculations. If you choose the latter approach, you may make simplifying assumptions, PROVIDING they are reasonable, conservative, and stated explicitly in your request.

In actual use and storage, some Xenon 133 will be released into the room from the storage and administration devices, rebreathing apparatus, collection systems, and escape from the patient. All sources of loss must be considered when estimating the fraction of Xenon 133 that is lost.

The following procedures may be used to calculate the air concentration of Xenon 133 in restricted areas:

- a. Estimate the maximum amount of activity to be used per week (A).
- b. Estimate the fraction of Xenon 133 that is lost during use and storage (f). This fractional loss must include ALL sources of loss, e.g., during patient administration, storage, and disposal.
- c. Determine the measured airflow rate in the area(s) of interest, and calculate the volume of air available per week for dilution of the Xenon 133 (V).
- d. For restricted areas, Section 30266 requires that:

$$\frac{A}{V} \times f \leq 1 \times 10^{-5} \text{ uCi/ml.}$$

### e. Sample Calculation

A nuclear medicine laboratory plans to use 10 mCi Xenon 133 per patient and will perform a maximum of ten studies per week. What ventilation rate is required to ensure compliance with Section 30266?

Maximum activity used per week:

$$\begin{aligned} A &= 10 \text{ mCi/patient} \times 10 \text{ patients/week} \times 1 \times 10^3 \text{ uCi/mCi} \\ &= 1 \times 10^5 \text{ uCi/week} \end{aligned}$$



Assume a loss rate of 20 percent (f)

$$\begin{aligned}
 V &= \frac{A \times f}{1 \times 10^{-5} \text{ uCi/ml}} \\
 &= \frac{1 \times 10^5 \text{ uCi/week} \times 0.20}{1 \times 10^{-5} \text{ uCi/ml}} \\
 &= 2.0 \times 10^9 \text{ ml/week}
 \end{aligned}$$

The required ventilation rate is:

$$\frac{2.0 \times 10^9 \text{ ml/week}}{40 \text{ hr/week}} + \frac{1.7 \times 10^6 \text{ ml/hr}}{\text{ft}^3/\text{min}} = 30 \text{ ft}^3/\text{min}$$

The answer shows that, in order to meet the requirements of Section 30266, the imaging room (RESTRICTED AREA) must have a ventilation rate of at least 30 ft<sup>3</sup>/min with no recirculation of air. Where practical, the ventilation rate should be greater than that shown necessary by the calculations. Consider every alternative in order to maintain the air concentration of Xenon 133 as low as reasonably achievable.

If the ventilation rate is inadequate to meet the requirements of Section 30266, consider methods of increasing ventilation or reducing the patient load.

The following table gives the amount of Xenon 133 that can be released per week without exceeding the permissible levels for Xenon 133 in restricted areas.

Ventilation Rate (ft <sup>3</sup> /min)	Maximum Xenon 133 Released Per 40-Hour Week (mCi)
100	67.9
500	339.7
1,000	679.4

## 6. Methods of Xenon 133 Disposal

### a. Dilution Through External Systems (Less Desirable)

One method for disposal of Xenon 133 is by release to the atmosphere through an air exhaust system. Licensees are required to perform surveys (measurements or calculations) to ensure that they are in compliance with Section 30269. The concentration of Xenon 133 in effluents to unrestricted areas should be as low as is reasonably achievable by the current state of technology, and Section 30269 requires that the concentrations, averaged over a period of one year, shall not exceed  $3 \times 10^{-7}$  uCi/ml.

Many facilities do not have sufficient airflow to achieve the necessary dilutions. The following procedure may be used to estimate the concentrations of Xenon 133 in effluents to unrestricted areas.

- (1) Estimate the maximum amount of Xenon 133 to be released per year (A). This should include all anticipated losses during administration, storage, and disposal.
- (2) Determine the flow rate of the exhaust system, and describe the methods and equipment used for measuring the airflow rates.
- (3) Calculate the airflow per year (V).
- (4) Calculate the average concentrations for unrestricted areas. Section 30269 requires that:

$$C = \frac{A}{V} \leq 3 \times 10^{-7} \text{ uCi/ml}$$

(5) **Sample Calculation**

A nuclear medicine laboratory plans to use 10 mCi per patient and will perform a maximum of ten studies per week. A fume hood is available for disposal of Xenon 133 and has a measured airflow of 168 ft/min with an opening of 8 ft<sup>2</sup>. What is the average concentration of Xenon 133 at the point of release from the fume hood exhaust? (NOTE: All xenon that has been released, e.g., collection bags, filter, must be considered.)

$$A = 10 \text{ patients/week} \times 10 \text{ mCi/patient} \times 10^3 \text{ uCi/mCi}$$

$$= 52 \text{ weeks/yr}$$

$$A = 5.2 \times 10^6 \text{ uCi/yr}$$

$$V = 168 \text{ ft/min} \times 8 \text{ ft}^2 \times 1.49 \times 10^{10} \frac{\text{ml/yr}}{\text{ft}^3/\text{min}}$$

$$V = 1.344 \text{ ft}^3 \times 1.49 \times 10^{10} \frac{\text{ml/yr}}{\text{ft}^3/\text{min}}$$

$$V = 2.0 \times 10^{13} \text{ ml/yr}$$

$$C = \frac{5.2 \times 10^6 \text{ uCi/yr}}{2.01 \times 10^{13} \text{ ml/yr}}$$

$$C = 2.6 \times 10^{-7} \text{ uCi/ml}$$

The following table gives the amount of Xenon 133 that can be released per week without exceeding an average concentration of  $3 \times 10^{-7}$  uCi/ml.

Exhaust Rate (ft <sup>3</sup> /min)	Average Release of Xenon 133 per Week (mCi)
100	8.6
500	42.8
1,000	85.6
1,500	128.4

If the exhaust is released to a restricted area, e.g., a roof to which access is controlled, or from a tall stack, Sutton's equation (Appendix Q. Other Resources, see Blatz and Cember) may be used to calculate the concentrations at the nearest unrestricted area. If this approach is used, describe the location of the exhaust system outlet, including proximity to unrestricted areas, air intakes, and open windows. Methods for controlling access to the area where the exhaust is located should also be described.

**b. Adsorption Onto Charcoal Traps**

This is the disposal method of choice. The advantage of this disposal method is that Xenon 133 is trapped onto charcoal or other absorbing medium. Filters containing Xenon 133 are then stored for decay.

One difficulty with this approach is that charcoal is not 100 percent efficient for trapping Xenon 133. If this is your method of disposal, you should consider the following points:

- (1) Describe how you will handle the problem of leakage from such trapping devices. If the exhaust is vented to the outdoors (UNRESTRICTED AREA), show the air concentrations of Xenon 133, averaged over one year, do not exceed  $3 \times 10^{-7}$  uCi/ml. (See example in item 6.a.)
- (2) Describe how you will ensure that collection and trapping devices are performing according to specifications, both initially and on a continuing basis. Include in your description how you will monitor traps to determine when saturation occurs and filter must be replaced.
- (3) Describe your procedures for handling saturated filters. Your discussion should include a description of the storage area (a diagram would be useful), available shielding, proximity to restricted areas, ventilation, and an evaluation of average concentrations of Xenon 133 in air. (See example in item 5.3.)

**USEFUL CONVERSIONS**

1 Mci	=	$10^3$ uCi
1 ft <sup>3</sup>	=	$2.832 \times 10^{-2}$ m <sup>3</sup> = $2.832 \times 10^4$ ml
1 ft <sup>3</sup> /min	=	$1.699 \times 10^6$ ml/hr
	=	$6.797 \times 10^7$ ml/40-hr week
	=	$1.484 \times 10^{10}$ ml/yr
1 week	=	168 hr

## APPENDIX P

### GUIDANCE ON REQUESTS FOR LICENSE AMENDMENTS AND LICENSE TERMINATIONS

#### 1. License Amendment Requests

##### a. Too Add a New User

- (1) Give California license number (with specific references as indicated in Item 6 of this guide) under which the person was previously listed as a user, if applicable; or
- (2) Give Nuclear Regulatory Commission or other Agreement State license number and include a copy of the license, if applicable; or
- (3) Send letter of request, attaching form RH 2000A or copy of appropriate certification (see Appendix C of this guide) if new user has not been previously approved for this type of license.

##### b. To Add Group 3

The following specific information should be referenced to the previous application or should be given special attention if it has not been previously submitted:

- (1) Calibration frequency, procedures, and standards for high-level survey meter capable of reading up to 1 R/hr.
- (2) Room diagram showing location of generator, kit preparation, patient dose preparation areas, etc., with special attention paid to shielding.
- (3) Use of syringe shields.
- (4) Method of assaying patient doses prior to administration.
- (5) Use of ring badges for personnel who elute generators, prepare radiopharmaceuticals from reagent kits, and prepare patient doses.
- (6) Daily survey of areas used for generator elution, preparation of radiopharmaceuticals from reagent kits, and preparation of patient doses.
- (7) Rules for personnel who elute generators or prepare radiopharmaceuticals from reagent kits to monitor hands and clothing after each procedure or before leaving these areas.

- c. **To Add Groups 4 and 5** (Group 5 is usually not available to private practice and clinics.)

The following specific information should be referenced to the previous application or should be given special attention if it has not been previously submitted:

- (1) Room assignment.
- (2) Instructions to nurses.
- (3) Procedures for handling contaminated linen and other contaminated items.
- (4) Use of disposable items, primarily for Iodine 131 patients.
- (5) Survey procedures, including dismissal survey.
- (6) Procedures for preparing oral Iodine 131 doses, including procedures for controlling and monitoring airborne Iodine 131 and thyroid uptake by personnel.

- d. **To Add Group 6**

- (1) Diagram of storage area with special attention paid to shielding and security.
- (2) Procedures for handling sealed sources.
- (3) Instructions for nurses.
- (4) Use of ring badges by personnel handling sealed sources.
- (5) Procedures for transporting sources from storage area to area of use and return.
- (6) Inventory procedures to ensure that all sources are accounted for after treatment.
- (7) Survey procedures. Dismissal survey, including radiation survey of patient and room after removal of sources, must ensure that all permanent sources are removed from patients and from those areas the patient occupied.
- (8) Safety precautions to be adopted if you plan to reuse radioactive seeds.

- e. **To Add Xenon 133**

- (1) Follow Xenon 133 licensing guidance carefully (see Appendix O to this guide).

- (2) Other concerns not expressed specifically in the guidance.
  - (a) Area in which Xenon 133 is used and stored should be under negative pressure.
  - (b) Air in these areas should not be recirculated back into occupied areas.
  - (c) All losses of Xenon 133 to restricted area should also be assumed to go to unrestricted areas. Concentrations in unrestricted areas must not exceed levels specified in Section 30269.

f. **To Move Nuclear Medicine Department\***

- (1) Provide diagram of new area (see Item 12 of this guide).
- (2) Provide survey results showing that all previously occupied areas are free of contamination and that all radioactive materials, radiation signs, and markings have been removed.
- (3) Specify the method of analysis of wipe samples, instrument used and its calibration procedure, and minimum detectable activity level.

g. **To Terminate a License\***

- (1) Submit a signed form RH 2558 indicating the disposition of the radioactive material. A signed letter may be submitted in lieu of RH 2558.
- (2) Submit survey results showing that all previously occupied areas are free of contamination and that all radioactive materials, radiation signs, and markings have been removed.
- (3) Provide the same information as specified in f(3) above.

\* A decontamination guide is available from the Department.

## **APPENDIX Q**

### **REFERENCES**

Title 17, California Code of Regulations (California Radiation Control Regulations)<sup>1</sup>

RH 2010R, "Well-Established Medical Uses"<sup>1</sup>

Title 10, Code of Federal Regulations<sup>2</sup>

#### **U.S.N.R.C. Regulatory Guides<sup>3</sup>**

Regulatory Guide 7.3, "Procedures for Picking Up and Receiving Packages of Radioactive Materials"

Regulatory Guide 8.4, "Direct Reading and Indirect Reading Pocket Dosimeters."

Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable."

Regulatory Guide 8.13, "Instruction Concerning Prenatal Radiation Exposure."

Regulatory Guide 8.18, "Information Relevant to Ensuring that Occupational Radiation Exposures at Medical Institutions Will Be as Low as Reasonably Achievable."

Regulatory Guide 8.20, "Applications of Bioassay for I-125 and I-131."

Regulatory Guide 8.23, "Radiation Safety Surveys at Medical Institutions."

Regulatory Guide 10.02, "Guidance to Academic Institutions Applying for Specific Byproduct Material Licenses of Limited Scope."

Regulatory Guide 10.5, "Applications for Type A Licenses of Broad Scope."

Regulatory Guide 10.8, "Guide for the Preparation of Application for Medical Programs."

#### **Other NRC Publications**

NUREG-0267, "Principles and Practices for Keeping Occupational Radiation Exposures at Medical Institutions as Low as Reasonably Achievable," Office of Nuclear Regulatory Research, USNRC, Washington, DC 20555.

## Technical Reports

Bureau of Radiological Health, "Radiation Safety in Nuclear Medicine: A Practical Guide," Department of Health and Human Services (HHS) Publication FDA 82-8180, November 1981.

Center for Devices and Radiological Health, "Recommendations for Quality Assurance Programs in Nuclear Medicine Facilities," HHS Publication FDA 85-8227, October 1984.

International Atomic Energy Agency (IAEA),<sup>4</sup> "Monitoring of Radioactive Contamination on Surfaces," Technical Report Series No. 120, 1970.

IAEA, "Handbook on Calibration of Radiation Protection Monitoring Instruments", Technical Report Series No. 133, 1971.

International Commission on Radiological Protection (ICRP),<sup>5</sup> "General Principles of Monitoring for Radiation Protection of Workers," Report No. 12, Pergamon Press, Elmsford, NY, 1969.

International Commission on Radiation Units and Measurements (ICRU),<sup>6</sup> "Certification of Standardized Radioactive Sources," Report No. 12, Washington, DC, 1968.

National Council on Radiation Protection and Measurements (NCRP),<sup>7</sup> "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides," Report No. 37, Washington, DC, 1970.

NCRP, "Protection Against Radiation from Brachytherapy Sources," Report No. 40, Washington, DC, 1972.

NCRP, A Handbook of Radioactivity Measurement Procedures," Report No. 58, Washington, DC, 1978.

NCRP, "Operational Radiation Safety Training," Report No. 71, Washington, DC, 1983.

NCRP, "Protection in Nuclear Medicine and Ultrasound Diagnostic Procedures in Children," Report No. 73, Washington, DC, 1983.

NCRP, "Use of Bioassay Procedures for Assessment of Internal Radionuclide Deposition," Report No. 87, Washington, DC, 1987.

NCRP, "Quality Assurance for Diagnostic Imaging Equipment," Report No. 99, Washington, DC, 1988.



## Standards

American National Standards Institute (ANSI,<sup>8</sup> ANSI N13.2-1969, "Administrative Practices in Radiation Monitoring (A Guide for Management)," New York, NY.

ANSI N13.4-1971, "Specification of Portable X- or Gamma Radiation Survey Instruments," New York, NY.

ANSI N13.5-1972, "Performance and Specifications for Direct Reading and Indirect Reading Pocket Dosimeters for X- and Gamma Radiation," New York, NY.

ANSI N13.6-1966 (R1972), "Practice for Occupational Radiation Exposure Records Systems," New York, NY.

ANSI N14.5-1977, "Leakage Tests on Packages for Shipment of Radioactive Materials," New York, NY.

ANSI N42.12-1980, "Calibration and Usage of Sodium Iodide Detector Systems," New York, NY.

ANSI N42.13-1978, "Calibration and Usage of Dose Calibrator Ionization Chambers for the Assay of Radionuclides," New York, NY.

ANSI N42.15-1980, "Performance Verification of Liquid Scintillation Counting Systems," New York, NY.

ANSI N44.1-1973, "Integrity and Test Specifications for Selected Brachytherapy Sources," New York, NY.

ANSI N44.2-1979, "Leak Testing Radioactive Brachytherapy Sources," New York, NY.

ANSI 44.3-1973, "Thyroid Radioiodine Uptake Measurements Using a Neck Phantom," New York, NY.

ANSI N323-1973. "Radiation Protection Instrumentation Test and Calibration," New York, NY.

ANSI N449-1974, "Guidelines for Maintaining Cobalt-60 and Cesium-137 Teletherapy Equipment," New York, NY, 1973.

ANSI N449.1-1978, "Procedures for Periodic Inspection of Cobalt-60 and Cesium-137 Teletherapy Equipment," New York, NY, 1978.

## Other Resources

Blatz, Hanson, Editor, **Radiation Hygiene Handbook**, McGraw-Hill, New York, NY, pp. 22-27, 1959.

Cember, Herman, **Introduction to Health Physics**, Pergamon Press, New York, NY, pp. 340-352, 1985.

Steere, Norman, V., Editor, **Handbook of Laboratory Safety**, chapter on "Determining Industrial Hygiene Requirements in Installations Using Radioactive Materials," pp. 482-502; also

"Basic Units of Radiation Management," pp. 391-426, CRC Press, Inc., 2000 Corporate Boulevard, N.W., Boca Raton, FL 33431, 1970.

Wong, Yen, Editor, **Handbook of Radioactive Nuclides**, Part VIII, "Radiation Protection and Regulation," CRC Press, Inc., 2000 Corporate Boulevard, N.W., Boca Raton, FL 33431, pp. 573-831, 1969.

Paic', Guy, Editor, **Ionizing Radiation: Protection and Dosimetry**, CRC Press, Inc., 2000 Corporate Boulevard, N.W., Boca Raton, FL 33431, 1988.

Brodsky, Allen, Editor, **Handbook of Management of Radiation Protection Programs**, CRC Press, 2000 Corporate Boulevard, N.W., Boca Raton, FL 33431, 1986.

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<sup>1</sup> Title 17 and RH 2010R may be obtained from the California Department of Health Services, Accounting Section/Office Services Section, P.O. Box 1525, Sacramento, CA 95807.

<sup>2</sup> Title 10 may be obtained from the Superintendent of Documents, U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20013-7082 or the National Technical Information Services, Springfield, VA 22161.

<sup>3</sup> Regulatory Guides may be obtained as in 2 above.

<sup>4</sup> IAEA reports may be obtained from UNIPUB, Inc., 345 Park Avenue South, New York, NY 10010.

<sup>5</sup> ICRP Reports may be obtained from Pergamon Press, Maxwell House, Fairview Park, Elmsford, NY 10523.

<sup>6</sup> ICRU reports may be obtained from ICRU Publications, P.O. Box 30165, Washington, DC 20014.

<sup>7</sup> NCRP reports may be obtained from NCRP Publications, P.O. Box 4867, Washington, DC 20014.

<sup>8</sup> ANSI standards may be obtained from the American National Standards Institute, Inc., 1430 Broadway, New York, NY 10018.

**INSTRUCTIONS:** Refer to *Guide for the Preparation of Applications for Medical Programs (RH 2010)*, Appendices, and *Listings of Affected Appendices to the Guide for the Preparation of Applications for Medical Programs* for more information. Complete items 1 through 28 if this is an initial application or an application for renewal of a license. Use supplemental sheets where necessary. Item 27 must be completed on all applications and signed. Retain one copy for your records. Submit original and one copy of the entire application to: State of California, Department of Health Services, Radiologic Health Branch, MS 7610, P.O. Box 997414, Sacramento, CA 95899-7414. Upon approval of this application, the applicant will receive a Radioactive Materials License issued in accordance with the general requirements contained in Title 17, California Code of Regulations.

NOTE: A Radioactive Materials License issued by the Department of Health Services to the applicant, pursuant to approval of the application, will contain terms and conditions based on information provided therein. Each licensee will restrict possession of licensed material to the terms and conditions of the use authorized in the license. Violation of any term and condition of the license may result in a license suspension or revocation. The terms and conditions may not be modified except by license amendment.

RH 2000 (10/99)

# INFORMATION REQUIRED FOR ITEM 6

Check the appropriate boxes for the groups requested and provide the required possession limit for each group below. If necessary, attach a separate sheet and provide any additional information; include Radioactive Material, form, possession limit, and proposed use. Identify the item number and the date of the application in the lower right corner of each page.

6. RADIOACTIVE MATERIAL FOR MEDICAL USE (Check requested groups)	Possession Limit (Check requested radionuclide and/or sources when applicable)
<input type="checkbox"/> Group 1 Diagnostic studies not involving imaging.	Total not to exceed _____ mCi.
<input type="checkbox"/> Group 2 Diagnostic studies involving imaging. (Check one or both)  <input type="checkbox"/> Unit dosage <input type="checkbox"/> Multidosage <input type="checkbox"/> Including the use of radioactive xenon as gas or gas in saline	Total not to exceed _____ mCi.
<input type="checkbox"/> Group 3 Use of radioactive materials and reagent kits for preparation of radiopharmaceuticals listed in Group 2.  <input type="checkbox"/> Including the use of bulk Technetium <input type="checkbox"/> Including the use of Mo/Tc 99m and/or Rb/Kr 81m generators	Total not to exceed _____ mCi.
<input type="checkbox"/> Group 4 Internal therapy not usually requiring hospitalization (outpatient).  <input type="checkbox"/> Including the use of Palliative treatment <input type="checkbox"/> Palliative treatments only	Total not to exceed _____ mCi. <input type="checkbox"/> I131 <input type="checkbox"/> Re 186 <input type="checkbox"/> P 32 <input type="checkbox"/> Sr 89 <input type="checkbox"/> Other:
<input type="checkbox"/> Group 5 Internal therapy usually requiring hospitalization for the purposes of radiation safety (inpatient).  <input type="checkbox"/> Including the use of Palliative treatment <input type="checkbox"/> Palliative treatments only	Total not to exceed _____ mCi. <input type="checkbox"/> I131 <input type="checkbox"/> Re 186 <input type="checkbox"/> P 32 <input type="checkbox"/> Sr 89 <input type="checkbox"/> Other
<input type="checkbox"/> Group 6 Use of sealed sources  <input type="checkbox"/> Brachytherapy  <input type="checkbox"/> Sealed sources <input type="checkbox"/> Seeds <input type="checkbox"/> Ophthalmic <input type="checkbox"/> Other:	<input type="checkbox"/> Cs 137 Total _____ mCi, in _____ source(s), no single source to exceed _____ mCi. Manufactured by _____ Model Number _____  <input type="checkbox"/> Co 60 Total _____ mCi, in _____ source(s), no single source to exceed _____ mCi. Manufactured by _____ Model Number _____  <input type="checkbox"/> Ra 226 Total _____ mCi, in _____ source(s), no single source to exceed _____ mCi. Manufactured by _____ Model Number _____
<input type="checkbox"/> High Dose Rate Afterloader	<input type="checkbox"/> Ir 192 Total _____ mCi, in _____ source(s), no single source to exceed _____ mCi. Manufactured by _____ Model Number _____  <input type="checkbox"/> Other (list): Source, total activity, number of sources, activity each source is not to exceed, source type, manufacturer, and model number.

6. RADIOACTIVE MATERIAL FOR MEDICAL USE (Check requested groups)	Possession Limit (Check requested radionuclide and/or sources when applicable)
Group 6 continued  $\pi$ Medium Dose Rate Afterloader	$\pi$ Cs 137 Total _____ mCi, in _____ source(s), no single source to exceed _____ mCi. Manufactured by _____ Model Number _____  $\pi$ Other (list): Source, total activity, number of sources, activity each source is not to exceed, source type, manufacturer, and model number.
$\pi$ Low Dose Rate Afterloader	$\pi$ Cs 137 Total _____ mCi, in _____ source(s), no single source to exceed _____ mCi. Manufactured by _____ Model Number _____  $\pi$ Other (list): Source, total activity, number of sources, activity each source is not to exceed, source type, manufacturer, and model number
$\pi$ Pulsed Dose Rate Afterloader	$\pi$ Cs 137 Total _____ mCi, in _____ source(s), no single source to exceed _____ mCi. Manufactured by _____ Model Number _____  $\pi$ Other (list): Source, total activity, number of sources, activity each source is not to exceed, source type, manufacturer, and model number
$\pi$ Ophthalmic treatments	$\pi$ Sr 90 Total _____ mCi, in _____ source(s), no single source to exceed _____ mCi. Manufactured by _____ Model Number _____  $\pi$ Other (list): Source, total activity, number of sources, activity each source is not to exceed, source type, manufacturer, and model number
$\pi$ Seeds	$\pi$ Au 198 _____ mCi in seeds $\pi$ I 125 _____ mCi in seeds $\pi$ Ir 192 _____ mCi in seeds $\pi$ Pd 103 _____ mCi in seeds $\pi$ Rn 222 _____ mCi in seeds $\pi$ Other: _____ _____ _____
$\pi$ Other (list)	$\pi$ Other (list): Source, total activity, number of sources, activity each source is not to exceed, source type, manufacturer, and model number



6. RADIOACTIVE MATERIAL FOR MEDICAL USE (Check requested groups)	Possession Limit (Check requested radionuclide and/or sources when applicable)
<p><math>\pi</math> Group 7 Diagnostic studies involving transmission or excitation.</p>	<p><math>\pi</math> Am 241 Total _____ mCi, in _____ source(s), no single source to exceed _____ mCi. Manufactured by _____ Model Number _____</p> <p><math>\pi</math> I 125 Total _____ mCi, in _____ source(s), no single source to exceed _____ mCi. Manufactured by _____ Model Number _____</p> <p><math>\pi</math> Gd 153 Total _____ mCi, in _____ source(s), no single source to exceed _____ mCi. Manufactured by _____ Model Number _____</p> <p><math>\pi</math> Other (list): Source, total activity, number of sources, activity each source is not to exceed, source type, manufacturer, and model number</p>
<p><math>\pi</math> Group 8 Use of sealed sources for treatment of cancer</p> <p><math>\pi</math> Teletherapy      <math>\pi</math> Teleradiosurgery</p>	<p><math>\pi</math> Co 60 Total _____ mCi, in _____ source(s), no single source to exceed _____ mCi. Manufactured by _____ Model Number _____</p> <p><math>\pi</math> Cs 137 Total _____ mCi, in _____ source(s), no single source to exceed _____ mCi. Manufactured by _____ Model Number _____</p> <p><math>\pi</math> Other (list): Source, total activity, number of sources, activity each source is not to exceed, source type, manufacturer, and model number</p>
<p><math>\pi</math> Group 9 Sealed or solid sources</p>	<p><math>\pi</math> Total not to exceed _____ mCi. Each source not to exceed _____ mCi.</p>
<p><math>\pi</math> Laboratory unsealed sources</p>	<p><math>\pi</math> List nuclide, chemical, and/or physical form and possession limit.</p>
<p><math>\pi</math> Blood irradiator</p>	<p><math>\pi</math> Total not to exceed _____ mCi. Each source not to exceed _____ mCi Manufactured by _____ Model Number _____</p>
<p><math>\pi</math> Pacemaker devices</p>	<p><math>\pi</math> Pu 238 Total _____ mg or _____ mCi, in _____ source(s), no single source to exceed _____ mg or _____ mCi. Manufactured by _____ Model Number _____</p>
<p><math>\pi</math> Other</p>	<p><math>\pi</math> Other (list) Source, total activity, number of sources, activity each source is not to exceed, source type, manufacturer, and model number</p>





## INFORMATION REQUIRED FOR ITEMS 7 THROUGH 25 AND ITEM 28

For items 7 through 25 and item 28, submit a detailed description of all the requested information. Begin each item on a separate sheet. Identify the item number and the date of the application in the lower right corner of each page. If you indicate below that an appendix to the medical licensing guide will be followed, do not submit the pages. *Applicant acknowledges changes in regulation may require the licensee to modify adopted appendices as to maintain compliance with Title 17, California Code of Regulations.*

<b>7. ALARA PROGRAM</b> π Commit to Appendix A <b>or</b> π Attach equivalent procedures	<b>16. A. PROCEDURES FOR MAINTAINING RECORDS OF RADIOACTIVE MATERIALS</b> π Commit to Appendix H <b>or</b> π Attach equivalent procedures  <b>B. LEAK TESTING OF SEALED SOURCES</b> π Attach detailed procedures <b>or</b> π Attach service contractor
<b>8. π RADIATION SAFETY COMMITTEE</b> (Not required for private/group practice) a. π Attach names and specialties b. π Commit to Appendix B <b>or</b> π Attach equivalent duties	
<b>9. TRAINING AND EXPERIENCE</b> a. π Attach form RH 2000A for each individual user or a copy of appropriate board certification (see Appendix C) b. π Attach form RH 2000A for RSO	<b>17. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL</b> π Commit to Appendix I <b>or</b> π Attach equivalent procedures
<b>10. INSTRUMENTATION</b>  π Attach Appendix D form <b>or</b> π Attach list; include types, number of each unit, ranges detected, efficiency of survey instruments, etc. (see guide)	<b>18. AREA SURVEY PROCEDURES</b>  π Commit to Appendix J <b>or</b> π Attach equivalent procedures
<b>11. INSTRUMENT CALIBRATION</b> a. π Attach Section 1 of Appendix E b. π Commit to Appendix E, Section 2 procedures survey instruments <b>or</b> π Attach equivalent procedures c. π Commit to Appendix E, Section 3 procedures dose calibrator <b>or</b> π Attach equivalent procedures d. π Commit to Appendix E, Section 4 procedures imaging equipment <b>or</b> π Attach equivalent procedures	<b>19. EMERGENCY PROCEDURES</b>  π Commit to Appendix J <b>or</b> π Attach equivalent procedures
<b>12. FACILITIES AND EQUIPMENT</b>  π Attach description and diagram	<b>20. WASTE DISPOSAL</b>  π Commit to Appendix J <b>or</b> π Attach equivalent procedures
<b>13. PERSONNEL TRAINING PROGRAM</b>  a. π Attach description of training b. π Attach description of residency program c. π Attach description of preceptorship program	<b>21. THERAPEUTIC USE OF RADIOPHARMACEUTICALS</b> π Attach description of dose preparation and administration π Commit to Appendix M <b>or</b> π Attach equivalent procedures
<b>14. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL</b>  π Attach detailed information (see Appendix F)	<b>22. THERAPEUTIC USE OF SEALED SOURCES</b> π Attach procedures as described in item 22, a-h of the Medical Guide π Commit to Appendix N <b>or</b> π Attach equivalent procedures
<b>15. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS</b> π Commit to Appendix G <b>or</b> π Attach equivalent procedures	<b>23. PROCEDURES FOR PRECAUTIONS FOR USE OF RADIOACTIVE GASES</b> π Attach information as described in Appendix O, 1-5 of the Medical Guide
	<b>24. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL FOR <i>IN VITRO</i> AND/OR ANIMAL STUDIES</b> π Attach detailed information



25. **PERSONNEL MONITORING** (refer to 10 CFR, Part 20, Section 20.1502)

TYPE (Check appropriate box)	SUPPLIER	EXCHANGE FREQUENCY
a. Whole Body <input type="checkbox"/> Film <input type="checkbox"/> TLD		
b. Finger <input type="checkbox"/> Film <input type="checkbox"/> TLD		
c. Wrist <input type="checkbox"/> Film <input type="checkbox"/> TLD		
d. Internal Dose Assessment (BIOASSAY): Provide detailed information (refer to 10 CFR, Part 20, Section 20.1204)		
e. Other (specify):		

**FOR PRIVATE PRACTICE APPLICANTS ONLY**

26. **HOSPITAL AGREEMENT TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL**

a. Name of hospital			
Mailing address (street, number)	City	State	ZIP code
b. Attach a copy of the agreement letter signed by the hospital administrator			

27. **CERTIFICATE**

(The individual executing this certificate must have the authority to commit the applicant relative to matters involved in this application.)  
The applicant and any official executing this certificate on behalf of the applicant named in item 1.a., certify: ***This application is prepared in conformity with the California Code of Regulations and all information contained therein, including supplements attached thereto, are true and correct to the best of my knowledge and belief.***

a. Applicant or certifying official name (type or print)	Title
Signature	
b. Date	Tax Identification Number

28. **FINANCIAL ASSURANCE**

(See Title 17, California Code of Regulations, Section 30194(g). **Attach one of the following:**

- ☐ Decommissioning Funding Plan
- ☐ Certification of financial assurance for decommissioning
- ☐ Statement of Intent (state or local government licensees)
- ☐ Rationale for exemption

The information you are asked to provide on this form is requested by the State of California, Department of Health Services/Radiologic Health Branch. This notice is required by Section 1798.17 of the Information Practices Act of 1977 (Code of Civil Procedure, Section 1798-1987.76) and the Federal Privacy Act to be provided whenever an agency requests personal or confidential information from any individual. It is mandatory that you furnish the information requested on this form. Failure to furnish the requested information may result in an inaccurate determination of statements and/or disapproval of your application.

**Note: This application will not be processed if the above information has not been provided.**

## TRAINING AND EXPERIENCE MEDICAL AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. Name of proposed authorized user or radiation safety officer			
2. Certification—Please attach a copy of certificate			
SPECIALTY BOARD	CATEGORY	MONTH AND YEAR CERTIFIED	
3. Training received in basic radioisotope handling techniques			
FIELD OF TRAINING A	LOCATION AND DATES OF TRAINING B	Type and Length of Training	
		LECTURE/ LABORATORY COURSES (HOURS) C	SUPERVISED LABORATORY EXPERIENCE (HOURS) D
a. Radiation physics and instrumentation			
b. Radiation protection			
c. Mathematics pertaining to use and measurement of radioactivity			
d. Radiation biology			
e. Radiopharmaceutical chemistry			
4. Experience with radiation (actual use of radioisotopes or equivalent experience) (Use back if more space is needed.)			
Isotope	Maximum amount per procedure	Duration of experience From                      To	Type of use π Diagnostic   π Therapeutic
Institution			Phone number (      )
Address (number, street)		City	State
Duties and responsibilities if Radiation Safety Officer (RSO)			ZIP code
Isotope	Maximum amount per procedure	Duration of experience From                      To	Type of use π Diagnostic   π Therapeutic
Institution			Phone number (      )
Address (number, street)		City	State
Duties and responsibilities if Radiation Safety Officer (RSO)			ZIP code
Isotope	Maximum amount per procedure	Duration of experience From                      To	Type of use π Diagnostic   π Therapeutic
Institution			Phone number (      )
Address (number, street)		City	State
Duties and responsibilities if Radiation Safety Officer (RSO)			ZIP code

**I hereby certify that all information contained in this statement is true and correct.**

Signature of proposed user

Date

**This part must be completed by the applicant's physician's preceptor.** If more than one preceptor, obtain a separate statement from each. (**NOTE:** Physicians who have obtained their Diagnostic Radiology, Nuclear Medicine, or Oncology board certification within the last five years need not submit the preceptor statement.)

1. Clinical training and experience

**KEY TO COLUMN C**—Personal participation consists of:

- a. Supervised examination of patients to determine the suitability for radionuclide diagnosis and/or treatment and recommendation for prescribed dosage.
- b. Dose calibration and actual administration of dose to the patient including calculation of the radiation dose and related measurements.
- c. Supervised interpretation of results of diagnostic studies.
- d. Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and therapy.

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets D)
	Thyroid scan		
	Thyroid uptake		
	Lung perfusion scan		
	Xenon ventilation study		
	Aerosol ventilation scan		
	Renal flow scan		
	Brain scan		
	Liver/spleen scan		
	Bone scan		
	Gastroesophageal study		
	LeVeen shunt study		
	Cystogram		
	Dacryocystogram		
	Cardiac perfusion scan		
	Cardiac stress ventriculogram		
	Cardiac rest ventriculogram		
	Gallium scan		
P-32 (soluble)	Treatment of polycythemia vera, leukemia and bone metastases		
P-32 (colloidal)	Intracavitary treatment		
I-131	Treatment of thyroid carcinoma		
	Treatment of hyperthyroidism		
Au-196	Intracavitary treatment		
Co-60 or Ca-137	Interstitial treatment		
	Intracavitary treatment		
I-125 or Ir-192	Interstitial treatment		
Co-60 or Ca-137	Teletherapy treatment		
Sr-90	Treatment of eye disease		
	Radiopharmaceutical preparation		
Mo-99/Tc-99m	Generator		
Sn-113/In-113m	Generator		
Tc-99m	Reagent kits		
Ir-192	HDR		
	LDR		
Co-60	Gamma knife		

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets D
Other			

2. Dates and total number of hours received in clinical radioisotope training

LOCATION	DATES		CLOCK HOURS OF TRAINING
	FROM	TO	

The training and experience indicated above was obtained under the supervision of:

Name of preceptor		Name of institution	
Mailing address (number, street)		City	State
Zip Code			
Materials license number(s)			
Preceptor's signature		Print preceptor's name	Date

## EXHIBIT 3

## PACKAGE RECEIPT AND MONITOR LOG

[illegible]

**EXHIBIT 4**

UNIT DOSAGE RECEIPT AND USE LOG FOR \_\_\_\_\_ AS \_\_\_\_\_

[illegible]



EXHIBIT 5

MULTIDOSE VIAL PREPARATION AND USE LOG FOR \_\_\_\_\_ AS \_\_\_\_\_

Manufacturer	Date Received Vial	Time	Date Dose Measured	Kit Source	Kit Lot	mCi/cc	cc	Measured mCi	Patient	ID Number	Initials

## MEASURING AND RECORDING MOLYBDENUM CONCENTRATION

[illegible]

## SHORT-LIVED IMPLANT SOURCE LOG

Received on: \_\_\_\_\_ seeds of \_\_\_\_\_ @ \_\_\_\_\_ mCi each  
 \_\_\_\_\_ seeds of \_\_\_\_\_ @ \_\_\_\_\_ mCi each  
 \_\_\_\_\_ seeds of \_\_\_\_\_ @ \_\_\_\_\_ mCi each

[illegible]

## SAMPLE CESIUM IMPLANT SOURCE LOG

Only the following individuals may handle these sources: \_\_\_\_\_

RSO: \_\_\_\_\_ Date: \_\_\_\_\_

## Normal Storage Configuration

1A	1B	1C
2A	2B	2C
3A	3B	3C
4A	4B	4C

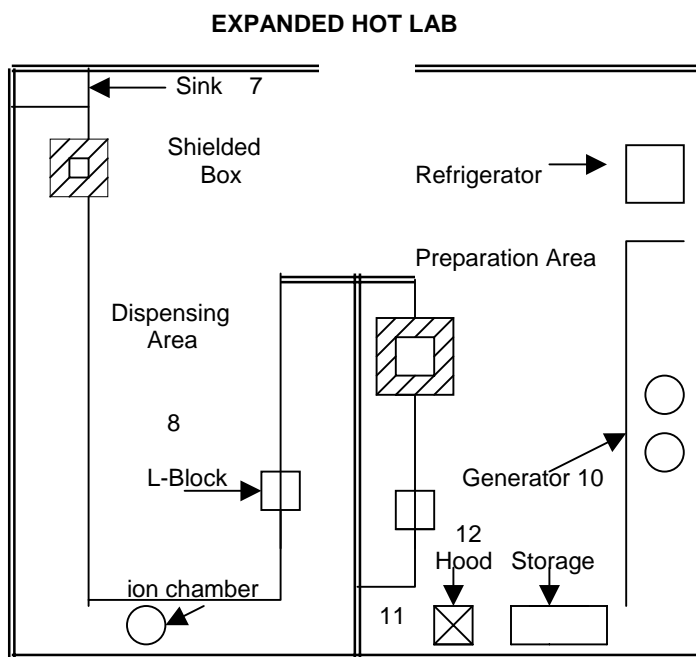
### Activity at Each Storage Point

20 mCi:	1A	1B	1C	2A	
10 mCi:	2B	2C	3A	3B	3C
15 mCi:	4A	4B			
5 mCi:	4C				

[illegible]

**RADIATION SURVEY FOR THE MONTH OF \_\_\_\_\_, 1989**

**Instrument:** \_\_\_\_\_



☐ mR/hr      or      ☐ dpm/100 cm<sup>2</sup>

[illegible]

**EXHIBIT 9**

**RADIOACTIVE SPILL REPORT**

This spill occurred at \_\_\_\_:\_\_\_\_ o a.m. o p.m. on \_\_\_\_/\_\_\_\_/\_\_\_\_, room \_\_\_\_.

Instrument used to check for personal contamination:

Meter model: \_\_\_\_ Meter S/N: \_\_\_\_ Probe model: \_\_\_\_ Probe S/N: \_\_\_\_

**Personnel Present**

**Personnel Contamination Results\***

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\*On the back of the sheet, indicate any personnel decontamination, additional monitoring, or care instituted.

Survey the spill area to identify hot spots, then begin decontamination. When finished, conduct a post-cleaning contamination wipe test.

Radioisotopes present or suspected in the spill:

\_\_\_\_ mCi of \_\_\_\_\_ as \_\_\_\_\_

\_\_\_\_ mCi of \_\_\_\_\_ as \_\_\_\_\_

\_\_\_\_ mCi of \_\_\_\_\_ as \_\_\_\_\_

Give a brief description of the accident: \_\_\_\_\_

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Give a brief description of follow-up actions taken to prevent recurrence: \_\_\_\_\_

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Name: \_\_\_\_\_ Date: \_\_\_\_\_

## EXHIBIT 10

### RADIOACTIVE MATERIAL DISPOSAL CONCENTRATION CALCULATION

1. DETERMINE TOTAL VOLUME OF SEWAGE PER MONTH: \_\_\_\_\_ ml

Note: The total volume of sewage may be estimated by averaging the volume as stated on a sewage bill or the volume of water used by a facility as stated on a water bill.

USEFUL CONVERSIONS:            1 cubic foot    =         $2.832 \times 10^4$  ml  
   1 gallon            =         $3.28 \times 10^3$  ml

2. DETERMINE AVERAGE ACTIVITY FOR EACH ISOTOPE DISPOSED OF VIA THE SANITARY SEWER PER MONTH:

ISOTOPE	ACTIVITY (MICROCURIES PER MONTH)
a. _____	_____
b. _____	_____
c. _____	_____
d. _____	_____
e. _____	_____

3. FOR EACH ISOTOPE, DIVIDE THE ACTIVITY (MICROCURIES) BY THE MONTHLY VOLUME (ML):

ISOTOPE	ACTIVITY	MONTHLY VOLUME	=	AVERAGE MONTHLY CONCENTRATION
a. _____	_____ uCi	_____ ml	=	_____ uCi/ml
b. _____	_____ uCi	_____ ml	=	_____ uCi/ml
c. _____	_____ uCi	_____ ml	=	_____ uCi/ml
d. _____	_____ uCi	_____ ml	=	_____ uCi/ml
e. _____	_____ uCi	_____ ml	=	_____ uCi/ml

4. TO DETERMINE COMPLIANCE WITH REGULATIONS, REFER TO: CCR, Title 17, Section 30287.

APPROVED BY: \_\_\_\_\_

DATE: \_\_\_\_\_

# EXHIBIT 11

## NURSING INSTRUCTIONS FOR THERAPY PATIENTS CONTAINING RADIOACTIVE MATERIAL

Patient Name: \_\_\_\_\_ Patient Number: \_\_\_\_\_

Attending Physician: \_\_\_\_\_ Phone: \_\_\_\_\_ Pager: \_\_\_\_\_ Patient Room: \_\_\_\_\_

Dose: \_\_\_\_\_ mCi of \_\_\_\_\_ as \_\_\_\_\_ was administered at \_\_\_\_:\_\_\_\_ ☐ a.m. ☐ p.m.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

### Radiation Exposure Rates

Unrestricted areas: door \_\_\_\_\_ mR/hr: room \_\_\_\_\_ mR/hr: room \_\_\_\_\_ mR/hr

Patient supine in bed or \_\_\_\_\_

Date	Time	Bedside	3 Feet from Bed	Door	
____/____/____	____:____ <input type="checkbox"/> a.m. <input type="checkbox"/> p.m.	_____ mR/hr	_____ mR/hr	_____ mR/hr	_____ mR/hr
____/____/____	____:____ <input type="checkbox"/> a.m. <input type="checkbox"/> p.m.	_____ mR/hr	_____ mR/hr	_____ mR/hr	_____ mR/hr
____/____/____	____:____ <input type="checkbox"/> a.m. <input type="checkbox"/> p.m.	_____ mR/hr	_____ mR/hr	_____ mR/hr	_____ mR/hr
____/____/____	____:____ <input type="checkbox"/> a.m. <input type="checkbox"/> p.m.	_____ mR/hr	_____ mR/hr	_____ mR/hr	_____ mR/hr

### Instructions

#### Visitor Restrictions:

- No Visitors.
- No visitors under 18 years or pregnant.
- \_\_\_\_\_ minutes each day maximum for each visitor.
- Visitors must stay behind line on floor at all times.

#### Nursing Restrictions

- Wear disposal gloves. Wash your hands after caring for patient.
- Discard linen, bedclothes, plates, utensils, dressings, etc., in designated container in room.
- Collect urine in containers provided. Discard feces in toilet.
- Housekeeping personnel are not permitted in the room.
- Only RSO may release room to admitting office.
- Wear your radiation monitor when caring for patient. Leave at nursing station at the end of your shift. Do not monitor. Call RSO for additional monitors if needed.

▪ \_\_\_\_\_

▪ \_\_\_\_\_

In case of emergency, or if you have questions, please call the following individuals:

RSO: \_\_\_\_\_ Work: \_\_\_\_\_ - \_\_\_\_\_ Home: \_\_\_\_\_ - \_\_\_\_\_ Pager: \_\_\_\_\_ - \_\_\_\_\_

MD: \_\_\_\_\_ Work: \_\_\_\_\_ - \_\_\_\_\_ Home: \_\_\_\_\_ - \_\_\_\_\_ Pager: \_\_\_\_\_ - \_\_\_\_\_



**EXHIBIT 12**

**RADIATION SAFETY CHECK LIST FOR  
DISCHARGED PATIENTS CONTAINING RADIONUCLIDES**

Name of Patient: \_\_\_\_\_ Age: \_\_\_\_\_

Address: \_\_\_\_\_ Telephone No: \_\_\_\_\_

Name of Person Interviewed: \_\_\_\_\_

Description of Dwelling: \_\_\_\_\_

In multifamily buildings, possible proximity of neighbors:

Household: Names, Relationship, Ages: \_\_\_\_\_

\_\_\_\_\_

Regular visitors to dwelling: \_\_\_\_\_

\_\_\_\_\_

Persons regularly visited by patient outside dwelling: \_\_\_\_\_

\_\_\_\_\_

Matters discussed:

- o Contamination control (toiletry, towels, disposable utensils, etc.)
- o Importance of separate beds
- o Importance of distance
- o Importance of special care in regard to young persons
- o Procedures in case of hospitalization or death

Identification card or wristband issued: \_\_\_\_\_

\_\_\_\_\_  
Date

\_\_\_\_\_  
Physician or Radiation Safety Officer

## INSTRUCTIONS FOR FAMILY OF RELEASED PATIENT

Name of Patient: \_\_\_\_\_

Name of Hospital: \_\_\_\_\_ Telephone No.: \_\_\_\_\_

Address: \_\_\_\_\_

For further information, contact: \_\_\_\_\_ Telephone No.: \_\_\_\_\_

Please show this form to every physician consulted concerning the patient until \_\_\_\_\_  
(Date)

\_\_\_\_\_ was treated on \_\_\_\_\_, 19\_\_\_\_  
(Name of Patient)

with \_\_\_\_\_ millicuries of \_\_\_\_\_ in the form of \_\_\_\_\_

**NO SPECIAL RADIATION SAFETY PRECAUTIONS ARE NECESSARY AFTER:** \_\_\_\_\_  
(Date)

### UNTIL THAT DATE:

Persons under 45 years of age should not remain closer than the following distances from the patient, for the time period indicated:

a. \_\_\_\_\_ to \_\_\_\_\_  
(Date) (Date)

b. \_\_\_\_\_ to \_\_\_\_\_  
(Date) (Date)

Permissible distance \_\_\_\_\_ feet or more for \_\_\_\_\_ hours per week. (At other times, remain farther than ??? feet.)

**Note:** During the above times, brief periods of closer contact (for example, while shaking hands, or kissing the patient) are permissible.

### SPECIAL PRECAUTIONS FOR EXPOSURE AND CONTAMINATION CONTROL

a. Spouse or other person caring for patient: \_\_\_\_\_

b. Children or pregnant women: \_\_\_\_\_  
\_\_\_\_\_

c. Sleeping arrangements: \_\_\_\_\_  
\_\_\_\_\_

**IF THE PATIENT IS TO BE HOSPITALIZED, OR IF DEATH SHOULD OCCUR, NOTIFY THE FOLLOWING INDIVIDUAL(S) IMMEDIATELY:**

\_\_\_\_\_  
\_\_\_\_\_

**A copy of this form should be kept with the patient's record.**

## AN ACCEPTABLE FORM FOR RADIOACTIVITY REPORT ACCOMPANYING BODY

\_\_\_\_\_ HOSPITAL

## Report on Radioactivity to Funeral Directors From Radiation Safety Officer

- o This body does not contain significant amounts of radioactive materials. No special precautions are required if standard embalming procedures are employed.
- o This body contains a significant amount of radioactive material. The following precautions are to be observed.

[illegible]

Signed: \_\_\_\_\_

Date: \_\_\_\_\_

# EXHIBIT 13

## NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH TEMPORARY IMPLANT SOURCES

Patient Name: \_\_\_\_\_ Patient Number: \_\_\_\_\_  
Attending Physician: \_\_\_\_\_ Phone: \_\_\_\_\_ Pager: \_\_\_\_\_ Patient Room: \_\_\_\_\_  
Dose: \_\_\_\_\_ mCi of \_\_\_\_\_ as \_\_\_\_\_ individual sources was loaded on \_\_\_\_/\_\_\_\_/\_\_\_\_

Sources will be removed at approximately \_\_\_\_:\_\_\_\_ o a.m. o p.m. on \_\_\_\_/\_\_\_\_/\_\_\_\_

### Radiation Exposure Rates

Unrestricted areas: \_\_\_\_\_ mR/hr: room \_\_\_\_\_ - \_\_\_\_\_ mR/hr; room \_\_\_\_\_ - \_\_\_\_\_ mR/hr

Patient supine in bed or \_\_\_\_\_

Date	Time	Bedside	3 feet from Bed	Door
____/____/____	____:____ <input type="checkbox"/> a.m. <input type="checkbox"/> p.m	_____ mR/hr	_____ mR/hr	_____ mR/hr

Release certification: Patient may not be released from the hospital until the following certification is signed and dated by the RSO or attending physician.

***I have removed and counted \_\_\_\_\_ individual sources from this patient. A low-range GM survey of the patient failed to indicate any remaining sources in the patient.***

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

### Instructions

#### Visitor Restrictions:

- No visitors under 18 or pregnant.
- \_\_\_\_\_ minutes each day maximum for each visitor.
- Visitors must stay behind line on floor at all times.

#### Nursing Restrictions:

- Patient is restricted to room.
- Patient is restricted to bed.
- No nurses who are pregnant may render care.
- \_\_\_\_\_ minutes each day per nurse in room.

#### Patient Care:

- Wear your radiation monitor when caring for the patient. Leave at nursing station at the end of your shift. You may use the same monitor on your next shift. Do not share. Call RSO for additional monitors if needed.
- If a source appears dislodged, call the attending physician and the RSO immediately.
- Omit bed bath.
- No perineal care. Pad may be changed as necessary.
- Save surgical dressings for disposal by attending physician or RSO.
- See special oral hygiene care instructions.
- \_\_\_\_\_
- \_\_\_\_\_

In case of emergency, or if you have a question, call:

RSO: \_\_\_\_\_ Work \_\_\_\_ - \_\_\_\_\_ Home \_\_\_\_ - \_\_\_\_\_ Pager: \_\_\_\_\_